HIT Standards Committee Meeting

June 30, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, and welcome, everybody to the 14th meeting of the HIT Standards Committee. Just as a reminder, this is a federal advisory committee, which means it's being conducted in public and there will be opportunity at the close of the meeting for the public to make comment, and the summary of the meeting will be posted on the ONC Web site. A reminder again for the committee members to please identify yourselves when speaking. And let's go around the table and introduce ourselves, starting on my left with Karen Trudel.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
Good morning. Karen Trudel, Center for Medicare and Medicaid Services.

Cris Ross – LabHub – CIO
Good morning. Cris Ross, LabHub Initiative.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Jim Walker, Geisinger Health Systems.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Stan Huff with Intermountain Healthcare at the University of Utah.

Martin Harris – Cleveland Clinic – Chief Information Officer
Martin Harris, Cleveland Clinic.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Carol Diamond, Markle.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
Steve Findlay, Consumers Union.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
John Derr, Golden Living.

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Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
Ann Castro, Blue Cross Blue Shield South Carolina.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jamie Ferguson, Kaiser Permanente.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Jon Perlin, HCA, Vanderbilt University.

John Halamka – Harvard Medical School – Chief Information Officer
John Halamka, Harvard Medical School and Beth Isreal ….

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Dixie Baker, Science Applications International.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Chris Chute, Mayo Clinic

Kamie Roberts – NIST – IT Lab Grant Program Manager
Kamie Roberts sitting in from … National Institute of Standards and Technology

Linda Fischetti – VHA – Chief Health Informatics Officer
Linda Fischetti, Veterans Health Administration.

Kevin Hutchinson – Prematics, Inc. – CEO
Kevin Hutchinson, Prematics.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
David McCallie, Cerner

Judy Murphy – Aurora Healthcare – Vice President of Applications
Judy Murphy, Aurora Healthcare

Mark Overhage – Regenstrief – Director
Mark Overhage, Regenstrief Institute and Indiana Health Information Exchange

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes Rishel, Gartner.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Nancy Orvis, Department of … Military Systems.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Walter Suarez, Kaiser Permanente

Sharon Terry – Genetic Alliance – President & CEO
Sharon Terry, Genetic Alliance

Judy Sparrow – Office of the National Coordinator – Executive Director
And on the phone I believe we have Rick Stephens. Rick, are you there?

Rick Stephens – Boeing – Senior VP HR
I'm here. Thanks very much. Good morning, with the Boeing Company.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. And Liz Johnson, are you there?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

I am. Liz Johnson, Tenet Healthcare.

Judy Sparrow – Office of the National Coordinator – Executive Director
Great, thank you. And I'll turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, Judy, and good morning everybody, and good morning to the people on line. Let me thank everybody for your continuing hard work. It struck me that at the beginning of the summer it looked like it might be a quiet period and as we look at today's agenda, this summer and the agenda before us is anything but quiet. I think this is going to be one of our richest discussions. There are areas that are potentially going to elicit some stronger feelings and passions. This is a meeting where we will really guide them to a broader … of many of the services that are necessary, both for privacy and security as well as moving to the interoperability of health information. That, to me, is tremendously exciting. We've spent the bulk of our time to date really considering medical use criteria and standards that support those, but the vision for interoperable healthcare really comes together when we make the same sort of evolution as occurred with personal computers to an Internet environment, to real power, to real opportunity. And of course, the real need for privacy and security occurs when information and data are exchanged between different points. That's why I think that today's discussion is both so terribly important and so rich.

Just working backwards through the agenda, I know in the clinical operations we begin to really evolve. What is the means by which we actually convey the richness of the clinical encounter in a way that other clinicians and other institutions and patients and all appropriate authorized users of health information can exchange information and know that they have both the depth of content and the reliability of that information in a way that serves that health need as a support for higher value healthcare.

As we move further towards the morning, and just after lunch, we'll have an update on privacy and security, and this strikes me as parallel to one of the nuances that has been very much a part of our discussion. As we fought and contributed to the policy committee and ONC's work and CMS's work in considering meaningful use, there's been this dynamic of discussion between, how do we actually get enough activity that we get toward really creating robust health information, but how does that also meter to the cadence that allows people to keep up? So there's a balance between the ambition and the speed of adoption, too slow, too fast. How do we hit just the right note? I know all of us wait with baited breath for the final responses on the two regs that are out, and we applaud and thank ONC and HHS for the response on the temporary certification process. That really helps provide a great deal of clarification. But one of those dynamics is that tension between speed of adoption, too slow, too fast.

The other thread of our conversations, one this group has been particularly articulate on, is the balance between lack of structure and highly structured. This is particularly important because in the absence of signal, we don't know where to go. On the other hand, with too highly specified a signal, it may also suppress the innovation and adoption that's possible. This discussion of privacy and security really needs the firm underpinnings of a set of services that are really the components of tools that all players in that exchange of health information can use to effect really 21st century information age business of healthcare. The clinical delivery of services, the patients right to information, the security around it, and the higher value that's supported. To be less oblique, we need to have a set of criteria that really help lead us to understand the set of services that can come together to create the privacy and security that really helps to underpin in information network.

This is a tremendously exciting and important time to look forward … governance. I know people have been watching the NHIN Direct, looking also with baited breath as well for the responses to the RFPs,

that come together to create the components of the NHIN environment. This is very exciting, because it then creates that Internet enabled connected world we very much need to support the ability of that architecture to exist with the specifications and standards that allow that commerce, if you will, electronic commerce in the interest of health information. And so I very much look forward to that discussion.

So these are the reasons I'm tremendously excited about this meeting. I think it's interesting work. I know that all of us coming to today's meeting know this is also extremely difficult work. It's going to take a lot of great thought. It's going to take a lot of work to really be sure that we think collectively about how we can contribute ideas to ONC that helps serve as an architecture in which as many as possible can participate. And that ranges, of course, not only from large organizations but to the patients whose threads of hope are pinned on the information that they can receive.

After John Halamka's opening comments we'll come to the minutes of the last meeting. Let me commend the ONC staff for really a very articulate and sensitive review. It's also a good premier for this conversation from our last virtual meeting, and many thanks to each of you who participated in that as well. So let me stop there and turn to John Halamka for opening comments as well.

John Halamka – Harvard Medical School – Chief Information Officer
Well, as you said, I think it's going to be a very interesting meeting. I think there's going to be some very, very rich discussion. When I blog, one of the things I talk about a fair amount is for everything there's a process. Now when I do a project, what's the process? Well, first, generally what I do is I define that there's some policy that serves as background for the project. The project has a set of aims. Those aims generally have objective criteria for success. Then you create a set of requirements based on asking what the business users need. You develop specifications. You then look at specifications in relation to the policy and the objective criteria for success. And then there's a governance process that ensures you're aligned the whole way.

I think as we talk about a number of themes today, the NHIN Direct activities, the NHIN itself, the NIEM framework, the Privacy and Security Tiger Team, there are some gaps, as all of us have exchanged e-mails and phone calls, in thinking through that logical succession of getting projects done. Do we have clarity on the governance of NHIN and NHIN Direct? When we talk about NHIN, is NHIN Direct a piece of it, a part of it? Is it tangential? Are there four NHIN projects? What is it? When we talk about the NIEM framework, that has a number of RFPs—well, where are we with those RFPs? How does this committee articulate those RFPs and ensure that as we go forward and ask questions, such as Jamie's, if we are going to have a harmonized approach to the content description of discharge documents of all various flavors, who decides? And what is the process by which harmonization occurs in a post HITSP world, and presumably we'll hear from Doug in the NIEM process and the RFPs exactly how we'll plug into that.

And then with the Privacy and Security Tiger Team, as you've mentioned, there are a set of services that may be offered in a health information exchange, and we want to make sure that there are policies that constrain services appropriately to project privacy, but don't overly specify so that commerce is restricted and innovation can't occur.

So for all these reasons of looking at, do we have a strong description of our objective criteria for success? Do we have governance processes in place on all the various projects in place? Hopefully, we'll come to the end of the day and say, —Oh, yes, actually we all understand broadly how this committee will plug in to every one of those projects and processes and have some go forward steps." And therefore, knowing all of you, this will not be a quiet meeting.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, John. I look forward to that rich discussion. Thank you for your leadership. Let me welcome Janet Corrigan from National Quality Forum who has joined. Has anybody else joined that we haven't acknowledged online or otherwise? Terrific. And I note that Dr. Blumenthal will be with us shortly. I know he's detained in some meetings currently but will be with us shortly.

I trust that everyone has had a chance to look through the minutes. Let me ask if there are any amendments, alterations that you see the need for. Okay, hearing none we will declare consensus on the minutes. Thanks again to ONC staff for putting that together. By the way, it's the first meeting without the presence of Jodi Daniel, who is a new mother. I wish her our very best.

Let's turn then to our first order of business. John, I don't know if you'd like to make any opening remarks and introducing Doug and Mary Jo.

John Halamka – Harvard Medical School – Chief Information Officer
Is Arien going to be joining us as well? Arien is the great voice from above, is what you're telling me. Okay. For this particular initial discussion, we know that the NHIN Direct project has been proceeding at a brisk pace over the last couple of months. Typically, the way that standards developments organizations work in this country is by consensus. You get a number of people who come together, they decide on best paths forward, and that does work. It achieves a result. Sometimes there are other ways one can do development, such as an agile software development methodology, where you simply, as I think NHIN Direct has described, come up with a set of requirements. You create running code; you try it, you test it, you move fast. And so what we'll hear today from NHIN Direct is where they are in this attempt to move fast and be agile and come up with creative ways for point to point transmission of data. I think the process over the last couple of months, Arian is working extraordinarily hard on it. There's been, I think, some political challenges, some governance challenges. There have been some proposals on trying to get convergence of multiple different approaches. So we want to hear from him as to where he is, where we can be helpful, where governance can help to get to a good result, and hopefully a role will be defined for the Standards Committee in reviewing a convergence that comes out of that activity against objective criteria provided by ONC for success, and then our feedback can be considered by ONC.

We'll hear from Doug on the standards and interoperability framework, the status of the RFPs and the NIEM process. And remember, the concept of operations document is supposed to explain clearly how all of this will work. So in the past, we had a small number of organizations that did all of these standards, harmonization, specification writing, test scripts, these sorts of artifacts being published, and now it's been divided into multiple RFPs. So how will all these RFPs work together, especially if they are given to multiple different organizations? And from Mary Jo, as Steve mentioned, the desire to engage us then NHIN Direct, and we should talk about, what is the scope of NHIN itself? Does NHIN include NHIN Direct governance, and how do we be most useful in advising ONC? So with that, take it away.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics Thank you very much, John. Again, I want to thank the committee members for coming out and participating in this. What I hope to do is a couple of things today. I want to give just kind of a brief reminder of the standards and operability framework that we're working on within the ONC. And then I'm going to give you just maybe one level down in terms of what we're thinking about with organization and coordination that's required to make all the pieces fit together. I have not queued up a whole lot of questions. I've found that this group doesn't need that. So I'm going to present some information and I expect that we'll probably have discussion with that as well. At the end, then, we'll also have Arien talk and give us an update about some of the work that's going on there. I guess, is Arien on the phone? I want to make sure that—

Arien Malec – RelayHealth – VP, Product Management
I am here.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Okay, good. Thank you. I don't have to channel you this time. So what I think is important is that I tried to keep this presentation at a level that really thinks about principles, things that we need to think about in terms of organization. Not so much into the down and dirty details about how we're going to do change management with our various versions and things like that. We realize that that's something important, but I want to be able describe to you some of the principles that we've got and see if there are things that we've missed or things that we need to include.

So we've talked about this before when we presented some of the standards and interoperability framework, and that is that we really want to try to create an ability to manage the lifecycle of the standards and the implementation specifications that were required to produce within the ONC. So we need to be able to take things in at the level at which people are describing in paragraph form the problems that they want to solve, the stories that represent the use cases, and then create a way in which those stories go from paragraph into more computational ways of viewing them, more explicit ways of describing those problems, so that we can then describe solutions, and describe what kinds of data or what kinds of services or what kinds of policies are needed to be able to support interoperability.

I think we also want to be able to reuse things, so that if somebody creates a use case or a service or a data element, we want to make sure that people have the ability to start not with a blank sheet of paper, but with some evidence that somebody else has already taken a look at, say, the attributes of a patient that are important for the exchange of information, and that we can then reuse that across the various stakeholders and business scenarios that might happen with that as well.

I think at the end, just as you do with software development, you want to have requirements capability that you can say, —This requirement for the software actually is met by this piece of code." We want to have the ability to have semantic traceability. We want to be able to say, this need for this data element, or this definition of this data element, actually is being carried all the way through so that when systems get developed, we know that the data listed in the database, or that the information that's being exchanged, can have its provenance traced back to what that definition should be. And that allows us to make sure—it doesn't give us interoperability for free, but it does provide a mechanism that we can simplify that process, because not everybody is starting with a blank sheet of paper. We're beginning to sort of create an environment in which we can build on other people's work.

So when we're thinking about how to organize this, I think there's a whole series of things, and we've put up here about five principles that we think are going to be important for how we structure this.

The first is representative participation. It's important that when we think about the standards and interoperability, that we have good representation from all the people who care about the work that goes on there, represented there. Now exactly how that all is going to work, and exactly what the structure of that, is something that I think is part of ongoing discussions. I'm not presenting you a final plan, but these are just the principles that we've been thinking about.

So we know that at every step, when we talk about developing use cases, when we talk about harmonizing those standards and sort of reaching consensus and unambiguous representations of the data, and when we talk about implementation specifications and how they might be used and tested, we know that there's going to have to be a spectrum of people that participate and provide input into that process. It's important that it's transparent and open. And so I firmly believe that what we need to do has to be out there in the public. We need to be able to have working documents that people don't get upset about or freaked out about. We need to be able to share things that are under review, and that means leveraging things like WIKIs and leveraging things where people can take a look and say, —This is in draft form and I don't agree with it, and I'd like it to be modified or changed." So transparency and openness.

But we also need to be responsive, and this is a challenge, I think, sometimes. We see this in some of the other projects and need to be able to move very quickly to develop things that solve people's problems, but at the same time, providing enough time for deliberative thought about things and to be able to get adequate input. And so, we need to make sure that we don't create an environment in which we become burdened by our ability to get that responsiveness. And so we need to have points in which there are decisions that need to be made, and that there are responsibilities, but at the same time, we need to have people free to do their work and to get things done, so that we can develop tools and resources for folks.

There needs to be accountability. Different people need to have different responsibilities for different parts of the process. So as we think about putting all these pieces together, ONC serves a coordinating

role in large part. But there are going to be the need for people who can be stewards, perhaps, that can shepherd things through this process and take accountability that it gets through the steps.

We also want to be able to make sure that we've got milestones and metrics, that we can predictably have processes that we can follow, that we can improve. There's always a tension. If what we do is produce a new thing every two or three weeks, it's very disruptive to people who are trying to actually develop systems. If we wait two or three years, it's also very disruptive because we don't actually move together. And so it's going to be important for us to think about how to organize the process so that we can get measurable, planned results as we go through things.

So you guys have all seen S&I framework before, and what we have here is, each of these boxes represents essentially an important task that we have within the S&I framework. And in large part, it corresponds to some of the contracts that are coming out within the next couple of weeks. So just to review, we've got use case development, in which we engage the community and we try to get the business scenarios. Those things then go from paragraph descriptions to UML models and other things that we can manipulate and harmonize using computational tools. Those then are used to assemble all those building blocks of core concepts and services into an implementation specification with good documentation. That's used then to develop a reference implementation to be tested in the real world, and then to serve as the foundation for certification and testing.

Now, we've got the NIEM snake down below there, that they have sort of this iconic view of things. What I've done is I've taken out those different colored boxes and I've put those up underneath the S&I framework. I think one thing that's important to recognize is that although the NIEM process sort of has this circular view, it seemed kind of water-fallish, that you're going to do one thing and then throw it over to the other. I've extracted that and I've put it up here, without the arrows and a just with the boxes, to emphasize that I believe this is going to have to be iterative, incremental. There's going to be the need to take small pieces and rapidly iterate through this process.

So if you think about it, when we talk about use case development and functional requirements, that maps into the NIEM processes of scenario planning and analysis of requirements. And so that will be a portion of the work that needs to happen. There's activities of mapping and modeling and building and validating, which basically say we're going to create the model, the UML diagrams or the IEPDs, the exchange packages, and we're going to make sure that those things map into the existing concepts that are there, or extend them in some way. All of that stuff needs to be then assembled, documented, and then put out to be published and implemented. And all of those tasks within the NIEM process can be mapped basically into the S&I framework.

I had another slide in here that I didn't include that put this into a rational unified process, where there were different phases, to try to emphasize that there's a lot of overlap here, but I thought having three slides all on the same thing may be more confusing. But I think the important point here is to recognize, we don't see this as being a sequential set of tasks, although we'll have to do that, but in fact, there's going to be a lot of iteration that is required.

What's missing from the NIEM process is two things. The first is that the NIEM process emphasizes data, and we need to be able to describe not only data, but the services and the behaviors that are necessary for exchange. Remember, when we think about the … we think about it in terms of the standards, the services and the policies. And so, a lot of the S&I framework is going to be to try to document and help articulate what those standards are and what those services are.

The other piece that is missing from NIEM framework is the notion of implementation testing and certification. So that becomes another piece, and one of the reasons that we've been working very closely with NIST around the certification process is that the farther up in this process we can engage NIST, so if NIST helps us with writing implementation specifications we can write them in a way that are clear enough to be articulated and that they can flow to certification. That eliminates a step of interpretation between implementation specification and how we might test it. So it's important here that when we think about the stakeholders and the folks that need to be involved in the framework, NIST and

our certification and testing, even though it's a box way at the very end of this presentation or on this slide, in fact, the NIST folks need to be involved at the very, very beginning of all of this, to make sure that that gets drawn all the way through.

So as we're thinking about this, and the people that need to be involved, we realize that if we engage them early, that helps prevent this sort of throw it over the transom to the next group, and we can begin to have those people that are going to be downstream participating in the work that's happening up front.

I've got another slide—remember, I said there were going to be two different slides. I didn't include the rough slide of this. But if you take a look at this, use case development, we've got scenario planning, analysis requirements and map and model, and that's all going to happen in some of our use case development and harmonization. Harmonization of standards is really going to be iterative, as we analyze the requirements and map it into the existing data elements and services that are described. There's going to be this interplay with this as well.

Implementation specifications and real world implementations is really about assemble and document, and build and validate, and that's where we'll generate the IEPDs, the UML models, the packaging for all of the artifacts. And we've already gone through a couple of iterations just to explore how we might package end services as well, to the packages that NIEM produces.

And then finally, we'll have emergent pilots testing the certification, and the need to publish these things into a repository. So we have to think about, if we want this to be something that is responsive and that can be done in the open and that can actually see our working code and the stuff that we're working on, it means that we're going to have to designate things as being draft, or designating it as working. And then we may also need to have some way in which we can say this has been reviewed. It's been tested. There's been a body or some group that has put their stamp of approval on it, and they've provided some feedback in term so whether or not this should be considered finalized or approved or the like. So we need to think through some of those things as well.

As I said, this is not meant to be a waterfall process. It's hard sometimes, without producing thousands of arrows, to be able to describe the kind of coordination that occurs. But it's important that we need structured coordination, and one of the things that we're working on right now is trying to determine, within this process, what are the kind of artifacts that we would see that would help us with coordination, so that at each stage there are certain kinds of artifacts that get produced that then can be reviewed by others.

What are the roles? Who owns different artifacts or activities, so that they can be assigned to make sure coordination, there is not duplication, and the process continues. One of the things that we've been thinking about with this is that although we can have essentially vertical responsibilities, there could be a group, and certainly within the contracting world, we're going to have groups that will be responsible, say, for use cases. One of the things we need is we need something that is horizontally coordinating through the process. And so this notion of a use case steward, somebody who says, —This is my use case. This is my problem I want to solve." It may be an individual. It might be an organization. It could be a group of people or organizations. But they say, —I'm going to make sure that this gets shepherded through the process, and at every step, make sure we're not getting off the case." And so this notion of a use case steward, to be able to shepherd this through, I think is an important aspect of this.

And then finally, we're working on developing control points, because we think that one of the ways we can be sure we're not getting off track, or that we're not getting either delayed or we're lacking in coordination, is to have certain points in the process that say, we need to stop. We need to make sure that we're on the right track, that there needs to be potentially a decision made or a review or approval for the next step. So we're trying to articulate where those control points might be in this process, so that we can have a smooth running operation and keep things on track.

So I tried to make this into a build slide, but it's a giant graphic and it was too complicated last night to try to pull it altogether. So I'm going to step through this by working horizontally and then down through the slide, so you'll just have to track with me as best you can with all of this.

If you take a look at this S&I framework artifact roles and controls, there's this notion of core artifacts that are going to be versioned, and really managed so that we keep the coordination. For example, we might have user stories that are used to generate use cases. We've got implementation guides that are going to be based on the use cases and the standards that you might have. You might then have test cases and testing infrastructure that are based on those various artifacts. And each of those artifacts has to get packaged up together, so user stories might have a series of capabilities listed, things that that user story is trying to do. That might be things like being able to exchange information on a clinical summary. It might be a capability that you might want to have, or the ability to verify eligibility for insurance. That would be another capability that might be listed.

There's also, when it comes to the IEPDs, we have to take the use cases, we have to take standards around data, we have to take other interoperability specifications and processes, descriptions of services, and those need to be packaged into an IEPD. We can think about those as releases that might occur, that meet a particular use case or can correspond to a particular user story.

There also has to be reference implementations that get released and packaged, and those should take the implementation guides that come from these IEPDs, and they need to be built into a reference implementation, and then packaged together so that people can take a look at them. This becomes important particularly when we're starting to talk about testing infrastructure. So if you think about the Nationwide Health Information Network, that NHIN Exchange, one of the ways that you test whether or not people can exchange information there is that you stand up a gateway that is a reference implementation and has a particular kind of functionality, and you say, does your gateway that you've just built, can it communicate with the reference implementation that we have?

So there's this need to be able to say, here is software that we've built, and we want to make sure that you can communicate with it. So that's part of the verification and release, and I'm sure that the NIST folks can talk a bit more about the importance of being able to have those kinds of tools that will allow people to test against it.

Each of the artifacts should have a responsible person that can manage that. So we imagine that within the S&I framework we're going to have a director who will manage a lot of the work that's going on within the framework, and they'll be responsible for the overarching coordination. I think the use case steward is an idea that has been presented, and I think it's a good one. It provides the ability to have someone who is committed to making sure that this gets through the process.

Remember, we've talked before about making sure that the S&I framework was built and driven by real needs and solving real problems, not in the abstract. So that use case steward is a person who cares about getting that problem solved. And by having that person follow this through, it makes sure that we're not messing up in terms of developing things, and we're not getting off track, because we're adding to it and we're adding all sorts of things that are maybe not in the spirit of what we wanted to originally solve.

We'll have to have someone who will help us with harmonization and what we call the specifications factory, the ability to sort of generate and develop those specifications. Currently we have a specification group that's doing some of this work, and it includes participation from NIST and other members as well, and that group has to develop those artifacts. There's a reference implementation that will need to be constructed. It's important to know as well if there's a divergence between the software that gets built and the implementation specifications. The right way to do this is to make sure that you change the software, unless there's a problem with the implementation specification. So often, if you run into a problem, if you say, ~~"~~Oh, well, this doesn't quite work, I think I'm just going to tweak it because I'm trying to solve a problem," if you don't feed that back to the implementation specification, you end up creating problems downstream for the next person who takes that implementation specification, and maybe solves

that same problem, but in a different way. Finally, we'll have testing leads, people that will be able to manage that as well.

So we've also then tried to identify where we think there could be control points, so one important control point is that if we have multiple different business scenarios and use cases coming in, we need to prioritize them. We need to figure out, if we've got resources to work on ten, and we've got twelve use cases, how do we determine which two need to wait? Or how do we manage that? There needs to be a use case publication, so people have an idea of where that is. There needs to be draft IEPDs that will incorporate the standards. There needs to be a stamp of approval of the reference implementation that says this meets the implementation specifications. We have to verify through the testing infrastructure that we got it right. And finally, we need to release that out as an artifact that people can use.

Now the thing is, this will take some time. It's not something we can do in six weeks. But it is something that I hope is not going to take us 18 months to go through this whole cycle. And the thing is that if we take a look at the NHIN Direct project, we're trying to accelerate that through, and we're going to try to do that in about 9 to 12 months. We're trying to get as much as we can forward. But I think part of the idea of openness and transparency allows us to point the way as to where we're going, even if we're not quite there yet.

A couple of other things, and then we'll turn it over to Arien here as well. When we think about the priorities and how we organize the work, I'm going to start at the top and work my way down here. We need to have a prioritized list of capabilities, and there needs to be a group that can help prioritize these high level capabilities. In a sense, this is the problem of saying we have 12 use cases and we have resources for 10. Maybe we need to get more resources to do the extra two, or maybe we need to try to prioritize it, but there needs to me a strategic body that says, this is where we're headed, and these are the things that will get us there.

Based on that, we need to have the ability to operationally prioritize what gets worked on as well. So this may be something that is a little lower down, but that's how we manage, say, a backlog of use cases, how we manage a backlog of specifications, and the various different teams that might be working. The challenge that we have in any process like this is at some point we need to have an operational organization that has principles that will allow us to operate within those bounds and get the work done. And the other is that we need to have broad impact with committees that are able to support this. It would be the difference between having a board of directors trying to run the day to day operations. We need to figure out at what point do we provide that strategic input, operational input, and a day to day function, as well.

So this is not by any means meant to be the way in which I perceive these things to work, but I want to give people a sense for the things that I deal with in terms of the kinds of standards and specifications that currently, as we speak now, are having to be managed within the offices of the national coordinator, and within the Nationwide Health Information Network. So we have priorities that are coming from meaningful use that come from the HIT Policy Committee that we need to develop recognized standards and develop implementation specifications as needed. But then, potentially we'll get approved by HIT Standards Committee. Certainly, Section 1561 from the Healthcare Reform Act has designate ONC to produce standards to help with insurance eligibility. And this committee is charged with reviewing those on the legislative mandate.

We also have work that is going on with VLER, the Virtual Lifetime Electronic Record, and that's a project between the VA and the DoD and some of the other partners. They have needs that specifications needs have changed, and that there are things that have to happen within NHIN that helps support their operational mission that they have within VLER. So we get requests that say we need to change this specification or we've identified a problem that needs to be updated. The specification doesn't work the way it's supposed to. And we need to incorporation that in as well.

The NHIN Coordinating Committee also has a need to be able to provide input into how specifications are written. Their current legal framework that they have gives them charge over how these implementation

specifications are written, and gives them the ability to prioritize those things. They also have an NHIN Technical Committee that reviews specifications and identifies new specifications that need to be constructed.

And finally, we have the federal health architecture. So beyond just the DoD and the VA and VLER, we have SSA, we have CMS, we have X12 transactions and other things like that, all of which have to coordinate if we want to be able to use the Nationwide Health Information Network, the services, standards and policies that are defined by that, in a cohesive way.

So I envision that we will have input from one side of the equation from a variety of stakeholders. We'll have a process in which we will develop these implementation specifications based on the principles that we've articulated. That we will try to make this something that is not waterfall, but is iterative and incremental. And that from that, will come our certification and testing criteria, and clear descriptions of the services, the standards and the policies that we need to help support this work.

So with that, I'm going to stop, and the next slide, Arien, since you're on the phone, is your first slide with the NHIN direct example. I'll turn it over. We can continue or we can stop here and have some questions, if that makes sense.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We'll take some questions at this point. You used the term board of directors. So let's imagine that this process which you've outlined has many moving parts and there are going to be things that iterate over the next couple of months. RFPs are going to be announced, processes will begin. Who is the governance overseeing that this process, end to end, is working and evaluating, and what is the role of this committee in that governance?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
We've been working very closely with the other NIEM teams that have essentially coordination processes as well that they have. Some of the folks that currently use NIEM use a federal advisory committee to provide very high level input into the process, but not necessarily detailed, day to day operations. They're sort of a coordinating group of key stakeholders pressed down one level in terms of their technical expertise. I have not put in this slide the specifics about how the NIEM process currently works in these other organizations in large part because I want to present to you more of a blank slate and get some discussion, so that we can go back and fill that in.

The big tension I think that we have is if every change to the model has to come back to the HIT Standards Committee, we will cripple our ability to be responsive and transparent. At the same time, I think it's important that when we make key decisions, that we have as broad of input as we can, and we can leverage that. So exactly how that all works, in fact I think NIEM has a high level … that provides strategic direction, but then when it comes to prioritization, they have another group, not really a sub-committee, but it's a group of concerned individuals, if you will, that are part of that prioritization process. It may be similar to the sorts of things that you would see with HITSP in terms of having the ability to coordinate.

Jonathan Perlin – Hospital Corporation of America – CMO & President
The reason I ask the question is suppose that all of us look at the work products that come out of this and say overly complex, hard to use, impossible to navigate. I'm not saying that will happen, but you'd want to say that there's some external oversight, ensuring that the work product is appropriate for the intended purpose and all those that you've articulated, open transparency, inclusive, all of that, that that's actually being done. So I would just hope that as you go forward with this, the governance with the HIT Standards Committee plugs in here.

Well, we've gotten in many, many comments, so why don't we start at the end there, Walter?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
This is Walter Suarez. A great presentation that I think things are maturing more and more. So as you mature things, more questions come up. I'll start with the organizing principles. I'm following up on John's comment. I didn't see a principle of consensus based decision making. It seems like there's a lot of pointing about representative participation, transparency and openness, but I think the critical element is going to be consensus based decision making. As a principle and as a define process, as John was point out, as to however the structure is. I think back for those that … the work on the HITSP project that was one of the most critical element, how do we achieve the decision about a particular recommendation from a particular work group or committed. So I would point to the development or establishment of that as a principle.

The second comment I have is I have read actually 10 of the 11 RFPs or task order or however we call them.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Congratulations.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Well, thank you. The important part I was trying to find was the first one, representative participation, the ability to participate. I was gladly noticing that in pretty much all of them, there is the intent that the entity that receives or is granted this task order is going to have the responsibility to convene stakeholders, convene subject matter experts. But the challenge, of course, is going to be that while before, we had one entity and all of us could participate in that, now we will have 10 or whatever number it is that we're going to be having to find resources and having to identify subject matter experts to participate. So I want to just point out the fact that this is going to be even more challenging to have organizations be able to participate in 10 different activities, while before it was primarily one major activity, HITSP for the most part. But I understand the interest of making sure that there is this deliberate process as defined in the all the old framework, but I just want to point out, again, the challenge that we will have to ensure that representative participation when we break even part of this structure of the framework into 10 different or 11 different task orders and 11 different points of participation.

And the last comment I wanted to make is, if I learned something about HISP it was education is paramount. I did not see necessarily any specific description or pointing to the education component that we will need across the board to help the industry understand all these products that are going to come out. I know there is a publish and implement element, and there is that, and testing and all that process, but it's going to be very important to deliberately define that as an element in this process, education and outreach and assigned resources, too. Of course, we do have extension centers and all the occasional elements that exist around that, but I think it's going to be very important to deliberately and explicitly state the function of the occasion, and outreach is one element.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Thank you. Those are excellent comments, and I've been making notes here as well. I think one of the things that's important is that I hope, once we have this all stood up, that this is not 10 different activities. It really is meant to have 10 different organizations supporting one process. So my goal here is that it would continue to have that kind of participation, but you wouldn't have to have 10 folks that would be participating in this. And the education component, I think that's an excellent suggestion. Thank you.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

Nancy Orvis. First of all, Doug, I want to commend you for actually building this straw man of the framework. Having been struggling with this internally for many years, it is a very good start on standards and interoperability. One of the things I agree with is that once organizations are faced with the need to exchange the information, I think the light bulb goes off for them that they are not in their own little world, and what they develop internally is not just in their own specifications and their own thing. And that, to me, has been—I think there's two aspects of development that I'm little bit concerned about.

This does focus on exchange, but there will still be the need to develop content in medicine and in biology, and that process, whether it's through Semantics and the National Cancer Institute and their metadata registry, and new concepts are developed every week, or there are new things being done in medicine, has to be addressed in terms of this development cycle too, because not everything that is going to be done is going to be a candidate for exchange through this framework at this point. So there will still need to be some standards, and the folks who need to work on that kind of information on new areas of medical knowledge. Whether you call that the R&D or the front end development, that has to be put somewhere, that those folks still have to have those folks engaged in that work while this is being done.

And the second point is, I'm not sure the whole group you're using to develop the ideas. I absolutely also agree that there is a use case steward. Internally, we've used the idea that there are these use case proponents. There are operational groups who collect the data or who make it happen, and there's an IT steward, like, where has that first happened? So that idea that you have somebody who really cares about what the endpoint is through this whole use case, that would be, I think, very effective. You have signed up proponents for each use case and say, like VLER would have particular use cases, the private industry and group practices might have certain use cases, the long term care industry might have a use case, so on.

So that's all I wanted to say. I think there are many of us who would like to help engage on developing this framework more, I'll just mention that to you.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I have colleagues who do what I do but for government in general, state and local government, and they're pretty impressed with NIN. They think it did the job in a substantial time, and their measurement is not how good were the specs but how much operation happened. I think that NIN had some extraordinary things going for it. Warren had a really compelling mission.

Two, it was doing Greenfield standards, and three, it came with money in the sense that the adoption of those standards was key to other money available to the states and local law enforcement departments. I don't think we get the same advantages. We don't have a 9/11 like event. We have a much more rolling and slow acting phenomenon that we're dealing with; equally important.

The first thing that I think is implicit in this program that will be an improvement over HITSP, and I want to confirm, is that in performing this process, the government will assure that all of the written artifacts developed are available publicly at no charge, and be able to be used to be edited into cohesive documents instead of the set of pointers to documents and pointers to lists of pointers of documents, which is what HITSP had to be satisfied with. Is that true? I see you making a note like maybe it will be true. No? Okay.

…direction was of course the fact that much of the intellectual property had to be licensed, and so a pointer to a pointer to a pointer. As opposed to, if you look at what SSA did in its … activity, it's just a document. Here it is. It's everything that a developer needs in one singular document, with examples

and test scripts. It's just right there. That would be great. HITSP had no choice because the artifacts that it was building from were produced by organizations that funded their work by selling those documents. So it was not a mistake in any sense, what HITSP did, it was just the limitations of the process it was given.

I have developed a new philosophy on consensus. I'm against it.

M
We all agree.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. I think that consensus works best when it is achieved by a small group of people over a short period of time. And it is very, just looking at the interesting set of meetings we had in NHIN Direct over the last month, there were people who said things about the bad … attempt to defend what they're already doing and things like that, but I honestly think that most of the issues related to people understood what they did, didn't understand the need for anything different, and therefore, had a hard time coming to conclusions. I don't think you can bring 100 people to consensus. I think you can bring 100 people to a decision that passes for consensus, but it's a different thing.

In the implementation alert group that … sponsored, we talked about what had worked in getting standards to be effective, and a lot of it—I'm going to rephrase now, but a lot of it was a Darwinian evolution of small group consensus ideas. So there wasn't the big impetus around, we're about to make a decision now that's going to affect the future of the nation and the welfare of dozens or hundreds of companies. It was, we're going to make a decision, we're going to get it out there, and then people will either flock to it or they won't. And that happens over and over again and an evolutionary path develops.

I recognize that we work in a world where our fundamental timeframes are driven by the election cycle and the span of attention of Congress, and as such, we have to commit to specific timeframes in order to create the credibility to carry a program over transitions in meta governance. So I honestly don't have specific advice to give here except let's try to do this in a small of steps as possible, and let's defer meta coordination of the whole thing till downstream until we have some idea what it is we're meta coordinating.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Thanks, Wes. I just have one comment. One of the things that we have and I didn't talk about the big blue box at the bottom about tools and infrastructure, in large part, if this can be government as a platform, where we provide the tools and resources that allow those small groups to innovate, but do it in a framework in which they can reuse and repurpose and share with others that are doing the same, that would be a good outcome of this. I don't know, Walter, you read all of the RFPs, but one of the things that's in every single RFP is the ability for me to write a detailed technical letter that redirects the contractors to work to develop tools and infrastructure to support them. So I wrote that in every single contract so that I had the flexibility to be able to redirect this towards things that will be infrastructure building and government as a platform.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Doug, if I could just add one other comment from the implementation group work in the past. We, in consensus operations, what I've learned over 30 years is that it's hard to build a consensus between those who are expecting to get something done in a timeframe and those who have more of an interest in the technology or the conceptual thing. I don't want to say you're avoiding consensus, but in managing how you go about getting consensus, I hope that this committee will not get isolated from those that are in

the frame of mind that we need this to work by a date certain, and I know what it needs in terms of process in order to do it.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well said. So in some ways, a platypus is a duck designed by consensus. David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
David McCallie. Doug, just a question. The previous slide you put up, where you … the stakeholder coordination was really helpful to me to have that one, because it relates, the activities that you're describing, to entities that are doing new things; that are either picking up old things or doing new things. And that's very helpful. What is unclear to me, or less clear, anyway, is how does what you're describing relate to ongoing, existing groups, like HL7, NTPDP, IEG? I mean, we have no shortage of groups that are doing stuff in parallel that is completely going to intersect with everything you do for these things going forward. So how do you intend to engage stakeholders who already are doing either the same thing or very similar things?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Well, as you can see, I didn't address that issue right up front. I think that there's a lot of different ways that that could happen. I think there is a clear recognition that we need to have engagement of those groups and participants. If I think about an implementation specification to help with electronic prescribing, I may need expertise from HL7, NCPDP, SNOMED, ICV9, and maybe, if we decide to do this in sort of a billing and administrative, maybe there's some X12 features that would fall into that as well.

So one of the challenges is that if you want, as John was articulating, that piece of paper or that document, or I would rather have the downloadable, executable files that you can ingest directly; if you want to have that, you have to be able to engage each one of those stakeholders in some fashion, because you're going to need all of them. And I think it's a challenge, and unsolved at this point, but certainly this committee can help us look at some of the issues and think through some of those issues as well. We have a mandate from ONB. ONB's circular A-119, if you want to know about it. But it basically says that the federal government should, to its preference, choose those standards that have been developed by standards organizations that are independent and consensus based. It's not the government's role to develop standards. Am I getting this right? Thank you, okay.

And so it's important for us, as part of this process, to think about it not so much as developing new standards, but sort of packaging them together to produce the implementations specifications that we need.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Will there be a role to drive those organizations in some way? In other words, I think your e-prescribing example is great example. All of those organizations exist, they all know that e-prescribing is a pressing need, and we still have huge gaps in nomenclature subsets and in choice of drug encoding models, and you name it. It's still a problem. Will this change that, or will it merely document that? I shouldn't say merely. Maybe it will be useful just to document it.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think that would be one step forward, if we were able to do that. Different countries have different models for how this works as well. Linda Shea has been great in trying to convene some of those folks and being able to take a look at what other countries are doing with this as well. I think we need to adopt a methodology and a process and a governance that is appropriate to the United States and the mission that we have within meaningful use and things like that. But other countries, they get them all together

and they say, we're all going to meet at the same time and we're going to solve some of these problems. We don't have that kind of convening or organization. It may be that at the end of the day that becomes something that we identify as a need and that the S&I framework provides a process and a mechanism to have that occur.

David Blumenthal – Department of HHS – National Coordinator for Health IT
This is David Blumenthal. Sorry to have been late. Doug is carrying the burden of answering some very tough questions, so let me jump in, either to confuse things or to assist him, I'm not sure which. But I think I can straighten him out there. The Congress was pretty clear what it wanted to happen when it enacted HITECH. It said that we should create a nationwide interoperable private and secure electronic health information system. It didn't say how that should be done, but it was very clear that it should be done. The … National Coordinator is tasked with making that happen. That means we need the standards to make that happen. I think that we are agnostic as to the process, but we're not agnostic as to the result, and that is that we have the responsibility to drive the development of standards in whatever way is most effective to realize that goal.

We are deeply appreciative and aware of the voluntary work that has been done … elsewhere, and of the many groups that are active in this area, and we want to continue to take advantage of them. But we do feel that there needs to be direction, and a program that will make it possible for people to be meaningful users of electronic health records. We have that responsibility. So we can't leave it to chance. The gaps that you've discussed are gaps that if they are critical to a nationwide interoperable health system, have to be filled. We can fill them by a consensus process or by bringing in groups, which would be great. But if that doesn't work we'll fill them some other way.

I see that as a very clear public mandate to the Office of the National Coordinator, one that we can't avoid. So I think there's kind of a dividing point in time that occurred with the passage of HITECH. It didn't say don't continue the consensus process, but it also said this is no longer something that is a matter of pure evolution. There are timelines around it. And Doug has been tasked with trying to create that process, and the NHIN governance process is in part an attempt to make a way of doing this that is the subject of public comment, that has all the attributes of an open and transparent government process for achieving a shared goal. But it's a new element. It's a new element that we are all going to have to adjust to. Everyone agrees on the goal. I don't think we've all come to agreement yet on the methods, but as long as the goal is out there, I think it acts as a discipline. Failure is not an option.

M
Thank you. I very much appreciate your comments, Dr. Blumenthal, which frames, I think, the context of my question. I should disclose that I chair ISO TC215 on Health Informatics, and therefore the question of internationalization, or for that matter leveraging previous work—I shouldn't focus myopically on ISO—but as we all know, there's a large body of previous work … and this is not a blank sheet of paper. So one of the question is, how would we leverage preexisting work? And two, to what extent, and this may not be the intent of Congress, but to what extent do we care about consistency and conformance with international standards? Do we want to have an American marketplace that is peculiar in some way with respect to HIT standards, or is there an interest in having a genuinely embracing and collaborative relationship with other countries and other international efforts?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think in large part, again, David has sort of framed the question. The charge that we have within the office, obviously, is the objectives that Congress set out for us. I think that becomes very focusing, and it helps us be practical in the work that we do. That having been said, you're absolutely right. There are lots of existing work that's been out there. And to the extent that those can help us accelerate the

process, I think they have to be incorporated and they have to be included in what we do. I think very practically about things like the standards that have been adopted in the IFR that has already been published. There are existing works that out there that represents those standards. Those are the first things that need to be incorporated.

I also think that one would hope that at the end, we have representational constructs that are if not identical to, consistent with some of the things that are out there as well. It may not be that implementation specification is internationalized, but part of what we're doing within the S&I Framework is to make sure that our contact representations conform to ISO 1-1179 standards, so that there is the ability to do some of that interchange.

So I think it's a critical thing to take a look at. I think it's part of the reason we've started some of the conversations internationally, to talk to folks that are operating in that sphere, but to make sure that we stay focused on getting the work done that we need to do, with an eye towards those other activities as well.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
This is Dixie Baker. This may be here. It's tiny print and it's tiny pictures so I may be missing it, but particularly, recent experience has shown me and some of my colleagues what can happen when you follow this process without appropriate policy in place, and I would like to see policy put in here. I don't think you can assume that policy exists going into the whole analysis and requirements and mapping and modeling. You will find instances where yes, policy exists, and other instances where it doesn't, and I don't think is should just be made up in the fly, because you'll end up at the end with a mismatch between what you have created and what needs to be there. So I would encourage you to look at these and incorporate making sure that policy is in place before you definitize the requirements.

M
Thank you. And just to give the group some concrete interpretation of what Dixie just said, imagine that a policy committee, like the Tiger Team or HIT Policy Committee says it need not be a requirement that a package of content be examined as it is transported from place A to place B. And that a standard is chosen by which it is guaranteed that the contents will be exposed as it goes from point A to point B. well, that would be, in fact, a technical solution that violates a policy principle. As long as one can constrain technology by stating policy up front, that would certainly be best.

Janet Corrigan – National Quality Forum – President & CEO
That was a great presentation, Doug. It looks like you made a lot of progress, I think, in sorting through all of this. A few comments. This issue of consensus is kind of an interesting one. Wanting a consensus based entity is, as I do for performance measures, and we operate under the National Technology Transfer Advancement Act, which is very explicit that consensus does not mean unanimity. It also doesn't even mean a super majority. Consensus means that you have defined a process that allows all voices to be heard and their issues to be carefully considered. So it's essentially a process. It is a process that has checks and balances each step of the way, that is incredibly transparent, and that provides the opportunity for people to bring issues forward and to see exactly how they were resolved, responded to, disposed of, whatever. But it absolutely does not mean unanimity, and never should, and probably shouldn't even mean a super majority, because it drives towards minimum standards as opposed to the kinds of standards that we really want. So I think it's important to think about this term of consensus and realize that people use it in different ways, and perhaps thinking more in terms of how the process is defined.

Now along the issue of the process, the one concern I had about your diagram, the stakeholder coordination one, which is great, is that—and it's not so much concern but just a point of caution. I think it's really important to very clearly and crisply define the roles of the various groups, because you've already got 8, and you'll soon have 10 or 15 different groups that are in place doing one thing or another, and those out there that don't like a decision at one level, if they can appeal it or take it to another, or

raise the issue again, they'll do it. And unfortunately what that sometimes means is that it just slows the process down unnecessarily. So I think it's important to be really clear where you need to have an appeal mechanism or a complaint mechanism, and there needs to be one there because there's no perfection in making these decisions. Sometimes mistakes and errors are made. But also, to crisply define the responsibilities of the groups.

So for example, if it's the standards committee's role, if there's going to be a separate group set up that's really going to consider the individual standards that are needed and put forward, you want to define the responsibility of this group to perhaps have oversight of that process to make sure that the integrity of the process is assured to handle appeals, or maybe you have another group that will do that. But to not allow a subsequent group to redo the work of the prior group, because that's exactly how you get into these really long timeframes that do slow the process down and make it very, very cumbersome.

It also is frustrating for the earlier group that thought it had responsibility for those decisions to then suddenly find that they're turned around our second guessed by another group. It really undermines their authority and their interest, frankly, in doing the kind of work that needs to be done.

And third, I want to go back to this point that was raised by David, I think, about what do you do when there are gaps in standards that haven't been put in place by the private sector standard setting organizations. I think it's really important that the government have both the authority, the mandate, and it sounds like they do, David, but the resources and the process in place, so that when you see that there is a gap that hasn't been filled by a private sector standard setting organization to your satisfaction, that you can fund it and sell it. Put the money out, get it developed, fill the gap, turn around and hand the standards over to the private sector group for ongoing maintenance, but have a process that really enables you to fill that and to do it in a very expeditious way.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I've just become a believer in telepathy, because Janet just made approximately the same points that I was going to make. I think consensus has been, in fact, mis-defined here as perfect agreement, and that's really not what consensus is. There does have to be a process for prompt consideration of objections, but that consensus is how you define that open, transparent process.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
I want to talk about the use case steward. I really like that idea. We use a similar concept—we call it a chief surgeon, about all the clinical people here. The one thing that I just wanted to stress, and it's probably already in your plans, but that role is useless without accountability and authority in order to dive into a lot of different parts of the organization on that continuum, the beginning to the end. It's almost a matrix-like position that's difficult to be in that position without—the person has to have accountability and authority to make the changes that are necessary, because groups will end up listening to other voices and have to be brought back to center. And of course, there is an escalation process, so that that's mediated fairly, but I just wanted to put in a plug for those two very important parts, or else it just won't work. We found that to be true in our organization.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
The good news is that there's a lot of consensus in the group about consensus. I wanted to just first potentially crack the record, Doug. On one of the things that you said, on one of the slides you said there are two things that are missing still in this framework, the services and the behaviors, because we said that NHIN was really about the services, policies and standards. And then you went on to say that we still need to work on the behaviors and standards, and I think what you meant to say was—correct me if I'm wrong—the services and the policies.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Let me just say, policies are a really critical piece of all of this, but the permanentization of the concepts and that process needs to be informed, as is been mentioned, by those policies. It's something that we've had some discussion about how does that fit into this framework and things? How do we represent them and things like that. So when I speak about things as two other things we have to work on, it means

that NHIN process to develop an IEPD doesn't have that. I don't know quite, and I'd be welcome, I don't know how to package a policy into the IEPD.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Okay, so I certainly appreciate that, and I also appreciate when you were talking about certification, how you said that really needs to be involved from the beginning, because you don't want to send it over the transom at the end, for all the reasons that were stated. And I think John gave a very good example. The same is true for policy. If there isn't a way to create a set of basic expectations on the front end, you can almost guarantee that you're not going to be able to influence policy on the back end. It's pretty much guaranteed, because the technical decisions always make policy. They just do. That's the way it works.

So I would encourage, and maybe this is part of the governance question, but I would encourage a process that incorporates not every last detail policy, but a high level set of policy requirements on the front end of any project that is setting out to create specifications for how technology is working. And let those two things be brought together as processes that move together through the process, because you learn things as you create the next set of specifications or you confront a problem, and the manager of those two processes is really what keeps both in check, from either one going off the rails. Policy can go off the rails too. So I would really encourage thinking about that.

The other thing I would say is, even for this committee, while we try to achieve consensus, if you will, and make recommendations, we are not ultimately the decision makers for what government does. Dr. Blumenthal and ONC and the government ultimately take input from us and make decisions, and I think the same expectation has to be factored into the kind of work that you're participating in now.

The last point I'll make about it, though, is that one, I think, very critical thing to consider, which makes ONC different from an SDL is that there's the need to think about the role of government. What is your role in that process, and what role should you play? You know, you mentioned the idea that one of the expectations that you had was that government would make sure that all the artifacts were publicly available. Those were the kinds of, I'll call it public interest, but those are the kinds of objectives that need to be factored into your role in this process. And I will tell you, I love Janet Corrigan's comments about, those are good examples where those kinds of requirements can override trying to get to unanimity or even super majority. And without those, I think sometimes you end up backed into corners that can be very uncomfortable. So all of these things, I think, need to be very strongly factored into the process.

Cris Ross – LabHub – CIO
I almost took down my card after Dr. Blumenthal spoke because it was clear what the direction is. But I still have a couple of questions that aren't' clear to me around governance. If the implicit critique of some of the comments around consensus is that we've gotten just sort of lowest common denominator, or gridlock consensus, as opposed to consensus that propels us forward, how does that received wisdom show up in this work? So it feels like there's two things going on here, one of which is, this is a softer development lifecycle process. And this is also a process for making decisions around standards and policies.

So my question really is around governance. The internal governance I think I get, and it seems to make sense to me the way that this framework can help push things forward in a better way. That's great. The question I've got really is around governance of scope, in terms of who will decide and when which use cases to take on? Who will decide when there's an important issue that should best be addressed by generating some working code or pilots or examples, and when that problem might be resolved by simply

saying, this is what the policy is for government agencies who are the private sector to take action, based on that set of policies? Because in some ways, we're doing a new thing, right? To Carol's point, working code becomes policy. I think to some degree, pilots become standards. So I wonder around that external governance regulation mechanism, how do you decide how far to go and when to stop?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think we will actually have some more presentations, when Mary Jo talks about the questions, about that broader external governance. So you may want to hold that question and after Mary Jo—

Mary Jo Deering – ONC
Let me answer it and get it off the table. That's exactly the kind of question we would like to include in the RFIs that I'm going to describe. I won't have an answer for you, but we're here to ask you, what are the questions we should be asking?

M
If that's the case, I guess I'd just like to find a way to bring that dialogue back into this process, because it looks, from an internal regulation standpoint, like it all makes sense. The question is really, I can imagine scenarios where this process, applied to certain sets of questions, could be problematic if there isn't a regulation mechanism or a governance mechanism around what use cases, for example, do we take on? And when does the policy come first and when does the pilot come first, those kinds of things.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We live in a governed universe, so you all were established by the Congress to advise the National Coordinator. The National Coordinator reports to the Secretary, the Secretary reports to the President, and the President works with the Congress. We'll come up with a regulation based on the best input that we have that will try to focus on the things that we think need to be done in order to move health information for patients' benefit in the U.S. healthcare system. If people don't like it, they can complain to their congressman, they can complain to the President, and they will hold me accountable, or my successor.

So we'll be making these decisions within a framework of governance that supersedes what we do in this room and in my office. But one thing we can't do is fail to proceed toward interoperability. That's just a given.

John Halamka – Harvard Medical School – Chief Information Officer
Jon Perlin wanted to make a comment, and I know, Wes, your card is up. If we could give Arien a chance to get through his presentation and then we'll open it up for comments again.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, John, and thanks to all of you for a terrific group process and discussion. I think the process itself is reminiscent of the points that were made about the role of consensus, is that I couldn't agree more with Janet Corrigan's comment in framing that what we need to do is support a process that leads to a responsible and a responsive outcome that's not necessarily based on unanimity, but informed by good policy and context. … David, you have a mandate. The HITECH is not an option, it's legislation, and it's pretty clear on what its requirements are. And to fulfill those requirements, you have brought forward a process which I applaud immensely to productize the services, policies and standards in the timeframe that Dr. Blumenthal alluded to.

So you have a challenge. You have to get from broad principles or use cases to a production system that delivers the services, policies and standards in a business frame. It's very reminiscent, if you think of an organization, information services organization that was building an operating system, you have to bring

those pieces together. In this instance, you're operating system is the nationwide health information system, where you have to translate that strategy into a series of operational or tactical actions. I think the metaphor that you used, very wisely, is that of the relationship between a board and its governance responsibilities, and it's role in the relationship to strategy is frankly, management. There is the responsibility for execution, and that, in principle and in fact, is the mandate given to your office. So I think that metaphor is very well advised.

We've talked about the aspect of consensus in that process, but there are a couple of other things that have come through. One is also a thread that I heard from a number of people, which is that process of translating strategy into operational activities and to deliverable products is really best predicated on policy driven criteria. And that in and of itself can help inform the relationship of the governance or board role to be delivering work responsibilities of management, for instance, your office and forecasts specifically. And so I hear that as a very clear thread, and that, I think, helps inform us what the roles of the different groups are, again, consistent with Janet's delineating both the need for that clarity and usefulness in achieving consensus, and having a process that dispatches not only what there is broad agreement around, but also giving a rational process for addressing and understanding those occasions when there is a differing viewpoint.

The other thread is that we're not starting with a total clean sheet. I think the NIEM process brings forward a degree of mechanisms for considering past products. Just to sort of … on this, there is a lot of preexisting work that can be incorporated. The challenge is not to be constrained by preexisting conditions to differentiate. So let me applaud. I think the … for a discussion that talks about that difference between the board role and governance, the relationship to policy driven criteria that helps to inform that, and the relationship to the management role to execute on these deliverables as they relate to the subject of standards, policy and services. So I thank you for that, and I think that's probably a pretty good segue into Arien and Mary Jo, unless you have any additional comments, John.

John Halamka – Harvard Medical School – Chief Information Officer
So Arien, give us the update on NHIN Direct.

Arien Malec – RelayHealth – VP, Product Management
Thank you very much, and I really appreciate all of the consensus oriented comments on consensus oriented process. I think the project that we're running in NHIN Direct demonstrates something to the pros and cons of such a process. I want to describe where we are and then how that fits in with the overall S&I process that Doug mentioned, as well as the key touch points with the various policy and standards advisory boards in the process.

We've been working since March on creating essentially the set of specifications or on drafting the user stories that are motivating the specifications, and then working on the specifications themselves. We're transitioning now into working on reference implementations and taking those reference implementations with appropriate policy guidance into pilot implementation. And working in parallel with the S&I process and the NHIN process on developing all of the key artifacts in that process. So we do have a set of essentially checks and balances on the work that we're doing in the indirect project itself in the more formalized process that Doug is putting together, and we're using the indirect project as a pilot, if you will, of the full S&I process.

In addition to the S&I checkpoint, there are a number of additional process checkpoints that we're working under. One is, and I've been really pleased to see the level of policy coordination that we've had with the policy committee, and in particular the Privacy and Security Tiger Team, and also the Standards Committee review, in defining the key policy considerations that go into the kinds of specifications that we're looking at. I think one of the key policy considerations that we're bringing into constraining the … definition relates to the point that was made earlier about letting transport be transport; that is engaged in getting a package of information from point A to point B, and being potentially blinded to, or the transport

level being blinded to what content is actually being transported. You'll see a little later on that we've definitely taken that key policy lesson to heart, and are making sure that these specifications we're working on are constrained by those policy considerations.

That Tiger Team is doing additional policy framework work that we need to see in order to move into pilot implementation, to make sure that those pilot implementations are appropriately grounded in the policy framework that's being worked on by the Tiger Team.

In addition, there was an initial Standards Committee review of the specifications they're working on, which I extraordinarily appreciated, which focused both on technical considerations and on policy considerations. I believe we'll need to do another round of that level of policy review, hopefully as the Tiger Team gets a little further along in the policy work, to make sure that we're staying in synch with the set of policy of guidance and recommendations.

And then finally, or not finally, but at least another step along the road is the Standards Committee has a legislative role in reviewing and recommending standards to HHS, and I fully anticipate that as we move into pilot implementations, we'll also come back to this body and present the findings from pilot implementations and present the findings from the S&I framework back to the Standards Committee for review and possible recommendations.

In addition, there's a whole set of additional criteria for inclusion in NHIN as a set of standards, that will be developed through the NHIN governance process that Mary Jo will be talking about, and of course, there's other standards governance evaluation functions that ONC takes on. And the main purpose of this slide is to say that we've got a work stream at NHIN Direct that's focused on getting to pilot implementations to solve a set of use cases that have been identified, but that there is no headlong momentum of that process into, for example, guaranteed inclusion in the NHIN, guaranteed inclusion in future certification criteria, guaranteed nationwide rollout independent of the policy framework. That the work that we're doing fits within a larger set of activities and has a set of process checkpoints within those larger set of activities to make sure that we're doing our job well and that all the key considerations that have been raised, both by this organization as well as the Policy Committee, are appropriately addressed.

So we've talked about the consensus oriented process, the pros and cons of that process, and the possibility of creating platypus, and the actual platypus. I think it's actually reasonably well adapted to its environment in Australia, but it does look a little funny. And it remains to be seen whether the work that we're doing is a well adapted platypus or a mal-adapted platypus. I think the consensus process that we've run has been constrained by two things.

Number one is we've got a consensus process that's actually constrained around a set of organizations that are ready and willing to do implementation in the real world in the short term. So it's not a consensus process that takes consensus for consensus' sake, it's a consensus process that is organized around a consensus of people who are ready, willing and able to do this. And honestly, I care less about, in this process, I care less about saying we have consensus, and that's an important value, than I do about actually providing the outcomes to providers that we're seeking to achieve in enabling direct communication for, for example, the coordination of care and transitions of care. One of the most important aspects or outcomes of decision making that we are trying to seek in the NHIN Direct process and project is decision making that leads to action, and that leads to the real world outcomes that we're trying achieve.

It is both a blessing and curse to be doing this work in the time in history that we have. When I went into the work I assumed we were going to get eight to ten organizations that would be willing to do this in the

real world in 2010. Instead we got 60 some organizations. The good news about that is that those organizations represent a wide range of stakeholders, including provider organizations from the very large to the very small; from a range of government oriented stakeholders, including federal providers, state and regional HI organizations; and then a whole set of HIT technology providers that serve a variety of markets, where the organizations themselves range from some of the largest technology organizations in the country, to extraordinarily small technology organizations, representing a variety of markets, again, ranging from single doc practices all the way up to the largest …. And then the process that we ran was a process that was designed to collect feedback and input from the lightest range of stakeholders, using both a set of calls and face-to-face meetings, as well as using technology, like WIKIs and mailing lists and the like that were designed to make sure that we're hearing from the widest range of participants.

Out of that process, we learned quite a bit, and I think we also learned some lessons in terms of how to run a consensus process. I think we've also heard about in the early discussions and reactions, to Doug's input. In terms of the support for the direct use cases that we're looking to achieve, we heard a lot of very strong support for services that need providers where they are, and recognition that we've got, in this country, a range of HIT adoptions, and need to support providers starting from where they are. One of the lessons that we learned is the need for use is primarily about providers who have adopted certified HIT technology, but that the business processes and the outcomes that we're seeking to achieve aren't limited to providers with certified HIT technology. That is to say that the transition care from a provider with certified HIT technology may occur to a provider without certified HIT technology, and so the support that we need to provide shouldn't be constrained around the need to providers with the most sophisticated HIT systems. But at the same time, we do need to provide an upward migration path to comprehensive interoperability.

We learned that the … that government has done and facilitated, and public partner/private partner organization facilitated, in HIPSP and the NHIN development work has actually been quite successful. We saw a range of ERH and HIT technology vendors who have strong support for the … profiled subservices, and how they desire that those services be a core part of the fabric of direct transitions in care and direct transport, going forward.

And then we also learned, and again, this has been a … of the discussion, that the existing healthcare standards, including the IEG profile standards, needs some work to be policy neutral for those uses. A number of people have mentioned that core standards mix the addressing metadata with the content metadata, requiring implementation to look into content metadata to figure out where that package needs to go, and those kinds of things need work.

The consensus proposal, and it was not a consensus proposal that required unanimous approval from all the members, but definitely a consensus proposal that requires listening to all of the key objections and all of the key sources of input, supports SNTP and S/MIME as the minimum background protocol. In many ways it's a little bit back to the future. It starts with the work that Wes and David originally did in simple … and that gives us a couple of things. It gives us a framework for universal addressing for providers and patients across the country. It gives us a secure framework for secure transport of health information. And it provides us strong separation of address metadata and consult metadata in a format that allows for the actual content payload to be blinded from the exchange, if the provider desires to operate in that fashion.

The consensus proposal endorses but does not require the use of strong content metadata, and that's important because we need to meet providers where they are, and those with sophisticated HIT technologies may be able to take advantage of work flow that is enabled by strong content metadata, but the providers that they're sending information to or receiving information from may not be capable of

generating or processing sophisticated content metadata. And so we need, again, to meet providers where they are, enable inoperability, if you can't get strong content metadata, but then be able to scale up to strong content metadata over time.

It's of course, the IHE FDR protocol that's used currently in admin exchange, and encourages development of exchanges to core … and a modified FDR specifications to support a bridge to an exchange. And again, that modified specification needs to address a point that's been raised a number of times regarding actually I think two issues. Number one is separation of addressing metadata from content metadata. And then the second issue is the ability to do transport even if the level of metadata that you're getting, the level of content metadata that you're getting, is de minimis.

The minimal specification that we're looking at is actually quite simple. It uses SMTP plus a MIME container at the edge with optional use and recommended use as the XDM content packaging format. So that's mode A. It allows for a mode B, the sender to send an already encrypted content payload, and make sure that that content payload is blind to the organizations that are doing the actual routing and transport. It supports at each of the connectivity points and requires each of the connectivity points an encrypted channel, so that no health information, and even no address information is exposed over the open Internet.

And the actual specification itself is quite simple. It primarily requires the implementation to figure out where the content needs to go. To do, if necessary, if it's not already been data encrypted, to do a signing and encrypting step in preparation for transfer in a way that guarantees that only the sender and only the receiver can participate in the exchange. That is to say, if I encrypt the package with the receiver's public key, then I can be sure that only that receiver, or authorized parties for that receiver, are going to be able to even view the content that's been transferred. And the proposal that we put in place satisfies some of the key policy considerations as well as trust considerations following open world recognized standards. On the receiving side, you hold the content encrypted, so that even if … after in the exchange wants to peek in and look at the content, they can't do so unless they actually hold the delegated private keys for the provider, for the receiving provider.

Then optionally require a decryption and verification step, again, if the receiving provider has delegated management of the keys to the exchange. If it does support a mode where the receiving provider can receive the encrypted and signed content and can do the decryption verification locally. And again, just repeat that provides a modality where from beginning to end, it is truly a point to point transfer, where the two exchanges are blinded to the information being transferred, although it allow if the provider wishes to delegate responsibility, it does allow for the exchange to do things like standard translation, content translation and the like, but again, at the receiving provider's choice.

So where are we going next? We are going to continue to collaborate with the Policy Committee and the Standards Committee to adapt a consensus specification and policy guidelines. I think it's also been a use best practice to look at the technology constraints and the policy constraints in parallel. And working on the privacy and security policy framework in concert with the technology work has, I think, been instructive to both organizations.

The project itself is going into high gear, working on documentation and testing; security and risk analysis; the development of an open source reference implementation; and I think most importantly, bringing this work out to providers in the real world for early implementation in specified geographies. We're also working with IHE to modify the XDR specifications to better meet the policy guidelines and user needs. And as I mentioned, those key policy guidelines are separation of addressing from content, and the usage needs are the ability to operate in the presence of minimal content packaging metadata.

So that's pretty much it. If we have time for it, I would welcome questions.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks very much, if we could just go back to the area of the second slide that showed the S&I Framework and timeline. Perfect. So I like this slide very much, Arien, because what you've talked about as checkpoints, or places the HIT Standards Committee can review the work in progress. Ideally, what we would like is to be informed by policy, the Tiger Team and the HIT Policy Committee, be informed by ONC as to the objective criteria for a success of this project, it's aims, and what you want to ensure you're achieving technically. And then for, as we did a couple of weeks ago with the objective evaluation, at the time waive policy and technology objectives and the give to ONC an HIT Standards Committee evaluation of the various reference implementations that you're working on.

So this governance, this baking into the process these checkpoints, where we can ensure there is a board of directors oversight—we won't meddle in your day to day, but we definitely, I think all of us from the conversations I've had, want that sense of a board of directors checkpoint in the process. So I really very much like the fact that you've baked this in, and not only do you have HIT Standards Committee, you have other standards governance and you have HIT Policy Committee and Standards Committees specification policy review that is a continuous process that actually goes from now until the end of the year.

One other comment and then we'll open it up. I imagine there will be a rich discussion here. What you really had was a tension that I certainly perceived in your process. On the one hand, you had a set of incumbents, and you wanted to engage those incumbents and you wanted to get rapid implementation because you had interested parties who were actually willing to go forward with technology solutions. On the other hand, in a green field, in a wonderful—we had to approach high tech and we just wanted to do this right and we had a set of objective criteria, it could be you would have had a different outcome than trying to achieve consensus of incumbents. I felt this in HISPE very often, which was, you would achieve consensus by those who joined the meetings. And that seemed great, but it wasn't necessarily in every case that you achieved your technical objectives based on the people who showed up to the meeting and agreed. So I'm sure you had that tension, and so welcome to my world.

Any comments you'd make on checkpoints or the tension that you felt?

M
Let me start at checkpoints first, because I think this is really critical. Again, I go back to this is not about technology, this is not about even process, this is primarily about achieving the clinical outcomes and the health outcomes and the quality access and efficiency outcomes that we're trying to achieve for all the people of the U.S. And having the right process checkpoints and having the right buy in from the … as well as from ONC, helps ensure that we're going to—we may go a little slower up front because there's more process review, there's more standards review that we need, but it should help us go faster where it counts, which is bringing the real world benefits out to providers in the end stage.

With regard to the second point, I actually don't see this primarily as around incumbents versus new entrants. There are a set of decisions that we might want to make from a pure technology perspective if we were sitting down and writing specifications in the basement. Again, I'm going to go back to my first point. What's most important to me in this process is achieving the clinical outcomes, achieving the outcomes for the country and the set of HIT's technology stakeholders that are in the process. One of the things that I've been very impressed by is that there is a strong desire to make this work in the real world,

and that desire extends from the technology organizations serving the largest health systems in the country, all the way down to the stakeholders and organizations serving the one and two doc practices.

I think we're starting to see a transition in the U.S. healthcare system where large systems and small practices are starting to feel themselves connected at the hip, from both a business perspective as well as from an outcomes perspective. And even from a technical, meaningful use perspective, you can't meet the meaningful use criteria without participation from all of the providers in your community that you refer to and from.

Which is a very long way of saying that if the set of decisions that we make in this process lead to the outcomes that we're looking for in the real world, then they'll be a good set of decisions, regardless of how individual people may have scored them from a technology perspective. If they don't lead to the those outcomes in the real world, then they're a bad set of positions, again, regardless of the technical merits…
So the process that we tried to work under and work with is really focused around achieving those business outcomes and clinical outcomes and efficiency outcomes in the real world, and I think that's how I'd like them, ultimately, to be judged, which, of course, sets me up for failure if we can't achieve those outcomes, but I do actually believe that given the participation that we've got and given the energy that we've got, that we'll get there at the end of the day.

John Halamka – Harvard Medical School – Chief Information Officer
Thank you. Let's go clockwise this time. So Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
This is Carol, and I really appreciate the focus on the quality outcomes. I would just add that I think ultimately, whether or not we achieve quality outcomes is less about agreement on technical specifications and their use and much more about whether we can, indeed, meet providers where they are, and whether people trust the system. And those two things are different constructs than merely the technical. All these pieces really do have to come together.

I wonder, my question is on the next slide, if we could go to the next slide, I do have a specific question. You said that this notion that transport and payload be separated, or at least the transport be accomplished with the payload blinded as a policy consideration that's consensus approach. But I heard you say that you want to allow the content and payload to be blinded, and that implies to me that there's optionality or a choice. So is the specification going to require that content and payload be blinded, or is it an option that people can exercise, depending on how they choose to implement some of the existing standards?

Arien Malec – RelayHealth – VP, Product Management
There's a set of policy considerations that are embedded in that, and I think the guidance that we've given from a technology perspective is consistent with those set of accepted recommendations from the Policy Committee. That's a complex non-answer, and I acknowledge that. The specification as we currently have written it requires that if you receive content that is payload encrypted, if an exchange receives content that is payload encrypted, it must accept it and it must deliver it without further modification. Which means that if the provider chooses to send essentially content that s going to the exchange, the exchange must be able to operate with that. On the receiving side, it also requires that if the destination has the capability of performing the PKI function of decryption and signature verification, it requires that the receiving exchange deliver that content to the provider in the form that the provider so chooses.

So the other part of this is that we're limited right now in the PKI distribution to end providers. And in the spirit of meeting providers where they are, we believed in the process that it would desirable to allow for the provider—and this is actually consistent with the Policy Committee's accepted recommendations—to delegate those functions to the exchange if they so wished. So if the provider has the capability and the means to take on the PKI functions of singing and encryption, then the exchange must essentially deliver content sight unseen. If the provider chooses to delegate those functions, for any number of reasons including the fact that they may not have the technical means to do the work, as well as, I think there are legitimate business interests where providers want to be able to, for example, get access to version translation services and the like, then they are at their request and at their delegation, their explicit delegation, they're allowed to do so.

So again, just to restate, the exchange is required to operated blinded to the content. The provider is allowed to delegate functions to the exchange at their explicit control, so that they can offload some of the technology work, as well as receive additional services from the exchange.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
So if the provider is delegating—is it a delegation to the exchange or a delegation to their edge system? I want to be sure I understand that.

Arien Malec – RelayHealth – VP, Product Management
They could delegate to either. If they delegate to their edge system, if they delegate, for example, to their EHR, then the exchange, in that context, is going to be blinded to the content. If their edge system doesn't have the technology means or technological means or they don't want to take on the PKI management, then they can delegate to the exchange if they so choose.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Okay, but we should just be clear then that the provider is not really making a choice. I mean, if they're participating in an exchange and the infrastructure of the exchange exposes the content, then they don't really have a choice at the edge.

Arien Malec – RelayHealth – VP, Product Management
No, they absolutely do. If they have the means and the capability of doing the work locally and of managing their certificates locally, and as we see, for example, the DEA prescribing rule work its way through the system we may see more and more providers who have the technology and the operational means to do that, then they can take on those functions themselves.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
It's been said that in meetings, the opposite of speaking is not listening but waiting to speak, and I'm guilty of that here in the sense that I'm responding to something Dixie said on the last round, where she was urging Doug to get—I hope I'm phrasing this as she meant it—urging Doug to get the policy work done first before developing a specification. I'm going to rephrase that in a way that I don't know that Dixie would agree with, but I want to make a point. She's actually asking Doug to create a waterfall situation between policy and requirements definition specifications, and I just don't think that works. I think that situations such as NHIN Direct require revising the agenda of a policy group in order to deal with a business opportunity. So there's a circularity there that has to be recognized.

Just to show that I was listening, I wanted to ask Arien a question about a hypothetical relationship between an HISP and a small practice, and tell me whether it's covered. You can put the diagram up—that one, right. Okay. So is it permissible, under this approach, for an HISP to say to a doctor, all you really need is a Web browser. You can log in and connect over TLS as you do with Amazon.com and

your favorite gaming site, and you can see lists of messages coming to you, you can create lists, you can upload attachments that might be structured data. Or is that ruled out? Because I don't see the SMTP between the edge and the HISP on this diagram.

Arien Malec – RelayHealth – VP, Product Management
Yes, it's absolutely permissible to combine the roles of essentially the EHR and the exchange. I think in that context what you'd be talking about is very likely a … module for the purposes of coordination of care. You may well want to combine that function with the exchange function. I think there are a number of organizations that will end up combining the EHR role and the exchange role.

The other point is that if you do that, then you're essentially combining both technologies under the control of the provider. You may also want to separate them out, so this diagram shows the fully separated mode, but you could have a mode where essentially the source and destination and the transport functions are combined in the same system. So there's only really two actors in that role. I think the short way of answering that was yes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. So to sum up, every HISP must communicate with every HISP by SMTP TLS, at least. So there can be no case where two HISPs are completely legal, but because they selected different options they can't talk to each other?

Arien Malec – RelayHealth – VP, Product Management
Correct. … is going to be able to talk to any other conformance ….

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. That there is optionality—I'm looking at Carol when I say this—optionality in terms of the way the HISP packages the business services it offers to the end users, is that correct?

Arien Malec – RelayHealth – VP, Product Management
That is correct.

John Halamka, BID
Dixie, did you want to make a comment in response to Wes' summary of your comments?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. And in response to Carol's as well, if you don't mind. I think in general a lot of our model doesn't work. System development in this day and age has got to be iterative. But in this particular case, we had four implementations developed before policy was addressed at all, forcing the policy people to be reactive and assess some policy assumptions that were built into the four implementations, and that shouldn't happen. The policy should be just as iterative as in any other decisions during a business development, but if policy exists to begin with, that policy should be factored into the process as both the mapping and modeling as well as the analysis of requirements. So that's my answer to that.

Jumping on to Carol's comment, I have two concerns about the exposure. One is the exposure for confidentiality, but the other is I have a concern about manipulation of information, which is more of a data integrity concern than it is a privacy concern. So on the one chart, Arien, you had endorses use of strong content metadata. I endorse the use of strong content metadata too, but I don't want, as a small provider, I want the option to allow the HISP to just encrypt my data and get it to the other end, and let the receiver do any application of metadata to my content if I want that to be an option. It's not clear to me whether that is an option.

Arien Malec – RelayHealth – VP, Product Management
Yes, it absolutely is an option. In fact, there is no requirement for any manipulation of the content beyond what's required for signing and encryption. Now somebody could add on the services, as you say primarily around the needs of the more sophisticated organizations who may want to receive content metadata in a consistent format, but we're not restraining or requiring the edge systems to do that work in order to accommodate the needs of a larger organization. So we're trying to constrain around the needs of the least sophisticated providers because we need all providers to be engaged in the process of coordination of care, while recognizing that more and more providers will actually have access to more sophisticated HIT, and that we should be forward looking, but recognize that we're living where we are right now.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I agree with that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
So the points have been made repeatedly, and believe me, we've heard it, that policy needs to precede technology. The other point that's made is that there can't always be a sequential process. It's an iterative, constant feedback between technology and policy.

I just want to make a point in defense of our Policy Committee, which is not represented here, and that is that we did do policy. Meaningful use framework is an enormous step forward in policy related to health information technology, and continues to evolve. Now there are areas in that framework that are less developed than others, and the privacy and security framework is one of them. So that is an area of such sensitivity and complexity that I suspect it's going to take a long consensus process before we actually have that ironed out. That's just a matter of fact, not necessarily intent. I don't know if we had the right to set privacy and security policy, whether we'd be very good at it. But I do know that this is something has to be done with a broad, complete, full involvement of the public. So we can solve some problems around this table or internally, but we can't solve them all. That's, unfortunately, or fortunately, just the fact of life that we're going to have to live with.

But in the mean time, you all, members of this group and others, have been working really hard with us to try to define the areas that we can. And in fact, we have been, as Arien said, in dialogue with the NHIN Direct group, and that has pushed us along in a very helpful way. So I just want to assure you all that we're aware of this issue, but there are just extraordinary sensitivities around the policy that make it very hard to drive it to a conclusion before it's ready to be driven to a conclusion.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
So I'm really encouraged by what's come out of NHIN Direct, and short of the IFR and the NPRM, I think the NHIN Direct is probably the most important thing that's going to come out of HITECH, simply because it's going to put data in motion. So I want to applaud the work everybody that's working on it. At the same time, I'm hoping this isn't the only chance we'll have to look at NHIN Direct, because I think it needs the … kind of conversations that Dr. Blumenthal was just talking about.

But assuming that this time might be a limited time, and we can comment on that, I guess two comments. If we go back to the previous slide, one is, in a reading through the consensus proposal, one of the things that concerned me is I don't think it was sufficiently clear on who bears the burden of the XDR activities. And that when we have that connection point between NHIN Exchange and NHIN Direct, it wasn't clear to me, again, who should bear that responsibility. It seemed sensible to me that the folks who were on the NHIN Exchange side of the fence should bear complete responsibility to do the transforms up and down,

to be able to get a message across the SMTP network, from a practical and a technical perspective. It's hard to imagine how you could do anything other than that. I had hoped this spec would be clear.

The second is, the first bullet point says SMTP and S/MIME as the minimum backbone protocol, but as I read it, it should be as the only backbone protocol, if I'm reading the spec literally. And I have heard lots of different opinions around whether that's the case or not, so the word minimum brings that into question. And this gets in some ways to a governance question. One of my concerns has been that the original users stories for NHIN Direct aren't going to be the only things we want to do with NHIN Direct. And that once we get past those initial user stories, there's going to be a requirement for bi-directional synchronous messaging that's not supportable by SMTP, and that one of the orphans that perhaps didn't get the nourishment it could have during the consensus process is the restful architecture that would easily support that.

Those are just comments intended to try to be helpful, to propel what I think is one of the most singular pieces of deliverables forward, and a way to try to be constructive; to not criticize the work but to try to advance it. I think we need to be crystal clear around who manages XDR, and I think we need to be clear around what transport protocols are allowed, either today or going forward. I think if we don't have a means to support, in the very near term, some bi-directional synchronous communication, we're going to have problems.

Arien Malec – RelayHealth – VP, Product Management
Let me address both of those issues. The first one, I think that goes to the comment that Dixie made and I'll repeat that I agree with you that the more sophisticated side of the exchange bears responsibility for managing need for additional content metadata. So I'm endorsing exactly the position that you're stating. I think it's represented; maybe the English isn't as clear as it could be in the consensus proposal but I do believe the consensus proposal acknowledges and agrees with that point as well.

With regard to the second point, it is a minimal backbone standard. It's a required backbone standard. The proposal does foresee that organizations may want to have additional means of getting information, additional policy compliant means of getting information from point to point, and so it endorses evolution and innovation, while requiring a certain minimal standard.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
So Arien, I know this is probably not the right venue for it. I guess I encourage further exploration around how you would do that evolution. I mean, Wes just raised a question in detail around how, with SMTP as the only transport protocol, you still have some important questions. If we add rest as an additional transport protocol, we'll increase by 10x the number of those similar kinds of questions, all of which are solvable. They just need to have a process and a venue by which do to it, other than saying in the future we'll get to it. I know that's not what you're saying, Arien, but it could be interpreted that that's the answer. I would like to understand how the governance process will continue to support that evolution.

M
It sounds like a good topic for future discussion. David and then Walter, can we just have a couple of brief comments, because I know Mary Jo, we do want to give you your time.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Just very brief comments. One with respect to the policy technology process, as a participant in NHIN Direct, I was very pleased to see that from the very beginning, there was a constant awareness of the technologists in the conversation of the policy issues, and an attempt to cleanly delineate what those policy issues were. We were moving fast enough that we couldn't stop necessarily and make a phone

call and say, what's the policy answer to this question? But we certainly went to a lot of effort to keep those cleanly identified so that when we did have a chance for review and cycling, that process occurred, and I think it's played out well. And many of the participants in NHIN Direct are around this table here today; many of them participate in standards, processes, that have wrestled with these issues for years and years and years. So it was a highly skilled group of people, so I think it has worked out well. The proof will be in the pudding.

The second is, to Carol's question, for better or for worse, we've landed on a model that is highly analogous to the way e-mail works, by design. So the issues around separation of clients and servers, and where they live and how they're hosted and how they're managed are really well understood. I think that gives us a lot of confidence that we know what the issues are, and that was, in fact, one of the strong arguments for following that e-mail like model.

So I have a laptop computer here in front of me. I'm running a Web browser talking to one e-mail server through a Web based e-mail server. I have a local client running talking to my corporate e-mail server. All are encrypted channels. And that's the exact model for NHIN that I think that Wes, your question about, could you have a Web based browser. NHIN Direct would allow exactly the same model that I have running here for my ordinary e-mail, with the difference that you would not be able to send unencrypted PHI in the NHIN model. It's further constrained past ordinary e-mail, so that you couldn't make the mistake of sending unencrypted or unprotected PHI. So I think that's a strength that we've modeled it after that. We'll see, but I feel pretty good about it.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Just a couple of questions and a comment on the process. The first one is that when I read the consensus proposal, it wasn't clear to me how this related to the standards that were adopted under the … final rules for EHRs. It gave me impression that for EHRs we were constraining the standard for encryption, or the applicability of the standard for encryption, and then opening the floodgates a little bit on the HISPs somehow. I might have read it wrongly, or might not have understood it correctly, but I just wanted to get your reactions about how this consensus proposal with respect to the adoption of the SMTP and S/MIME and SVR relates to the standards that were adopted in the IFR. That's my first question.

Arien Malec – RelayHealth – VP, Product Management
Sure. The intention I believe for the final product is completely consistent with the IFR in terms of requiring all content to go over encrypted channels, and also in terms of the technical requirements for the encryption and hashing that exists in the IFR. So there is no modality that's foreseen in the specification by which data can be transitioned or transferred in the clear, and the requirements are consistent with the IFR requirements for encryption and for hashing.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
So I would recommend perhaps adding a statement to that regarding that, in the document, so that it makes the connection back to the standards the way adopted in the IFR, just to clarify. I don't know if others might have—

The other question I have is about, and you mentioned it or the proposal mentions that SMTP is sort of a stepping stone on the NHIN Exchange. But how does current NHIN Exchange differ from the consensus proposal?

Arien Malec – RelayHealth – VP, Product Management

That's a little complex a question, because the NHIN Direct project has no right to speak for NHIN Exchange. There's an interim governance mechanism for NHIN Exchange, and then a to be final governance mechanism for NHIN Exchange, and we need to respect that governance process and governance mechanism. What we're recommending is that two things happen.

Number one is there be a change to the technical specification that NHIN Exchange uses to separate out the addressing metadata from the content metadata. Right now on the XDR specification they're mingled.

The second thing that we're recommending is that there be an explicit way of carrying all the key content that we're talking about over that native transaction for an exchange, and that the NHIN Exchange participants use that transaction essentially as their backbone. That's already what they're using. But again, just to speak really clearly, we don't have the right in the NHIN Direct project to dictate or say how the NHIN Exchange should function, and we would expect that we'll make some proposals and go through the normal governance processes for NHIN Exchange, for accepting or rejecting that proposal.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Okay. My last comment is rather process, but I saw the consensus proposal, I think it came up on the … on Monday. It might have been someplace else, but the request for comment was due today, or the request for consensus, really, I suppose. So it's a little bit of a short timeframe with organizations like ours, trying to figure out how to quickly provide a response and feedback. Is that correct, the deadline is today for comments and for basically consensus agreement?

Arien Malec – RelayHealth – VP, Product Management
It is correct that the deadline is today. We have noted that organizations need additional time and can request that. I'd also say that this is the culmination of a lot of work that's gone on for months. So the final words got into the final shape quite recently, but the concepts that we've been talking about we've been discussing for quite a while, with lots of give and take. So if you need more time, feel free to let us know and as long as it's reasonable we'll extend the timeframe.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
We do need more time. Thanks.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I want to thank Arien for his terrific leadership on this topic, Doug too. I also want to make it clear that I can say some things that Arien can't say. It is absolutely our intent that there be a path of evolution from the NHIN Direct to NHIN Exchange, and that the processes that are built into NHIN Direct be compatible with Exchange.

Now having said that, I can't tell you how that's going to happen. Maybe if I were smarter about standards I could, but I'm not. But if you want policy, that's policy. So that's what we want. Because we are intent on supporting our federal partners and the states, and the other private organizations that have adopted NHIN Exchange and are trying to use it, we see it as a very important exchange option, one that has many features that are desirable. But in the spirit of meeting providers where they are, it isn't adequate in itself. But it is an important commitment of the … National Coordinator, and it makes no sense to elaborate solutions to the Exchange that take providers on incompatible courses that don't cost. That's an important issue too.

If anyone around this table thinks that things are evolving in a way that makes that impossible, or will frustrate it, we very much want to know that. We understand there's uncertainty about how it's going to

happen, but uncertainty is different from reaching a conclusion that it can't happen or won't happen. So we want your advice on how to make it happen, but Doug and Arien, I hope and trust, will continue to work at that, but that's our intent.

Jonathan Perlin – Hospital Corporation of America – CMO & President
What David has outlined is a need for governance, so I recognize we have used quite a bit of your time, but this, I know, is a very, very important discussion for us to get all of these issues on the table. So that's very much, Doug and Arien, and Mary Jo, please, take it away.

Mary Jo Deering – ONC
Well, I actually view this as a very productive use of time, because I firmly believe that almost all of the discussion that's gone on this morning would have taken place after my presentation, had it not taken place beforehand. In fact, I'm going to credit Cris Ross with succinctly framing the meta governance question for this group, what is the governance framework that needs to be put in place for the development of standards and specifications and other technical issues? But let's get there later.

In fact, I'm going to bump the discussion up to a higher level, because I am delighted to be here to finally begin to engage you in this critical issue of developing governance for the nationwide health information network. I do want to echo and reinforce or pick up on what David said, which is there is but one NHIN and all are one in it at the end of the day. The only reason we are talking now about, and Arien mentioned a separate governance mechanism for the NHIN Exchange, is that we are in rule making. At the end of rule making there will be one comprehensive governance mechanism, flexible albeit, but there will certainly not be entirely separate mechanisms for different types of projects.

And again, because this is such a complex issue, we're going to be seeking multiple points of input along the way. So today I'm actually here to engage you in that very first step, which is we do want to go out in early August with an initial request for public comment, and we'd like your input on what should we ask for in that RFI? We're going to be aiming for an NPRM early in 2011, followed by a filed rule in the summer of 2011. So last week we spoke to the Policy Committee to get their input and guidance on questions relating to the policies and services and those aspects of the NHIN, and today we're asking you to do what you already spent an hour and a half doing, which is looking at, what are the questions that you need to ask to get to the right kind of a framework.

Now some of you may remember that ONC has actually been looking at governance since 2004. We put out an RFI about the NHIN back in 2004 and it had governance questions in it, and so you probably commented. I'm sure … commented back then. So the slides that I'm presenting today, as high level as they are, they do reflect a lot of work over the years, but even, of course, more recently and more importantly, the work of the two, … and Tiger Team to date. So again, the slides that follow especially tee up these higher level questions. A few are fairly specific. We don't want you to answer them today. We know these aren't necessarily all the questions; we know they might not even be the right questions, but again, it's a way to begin to get your first guidance.

There's only a single line in HITECH that says the national coordinator shall establish a governance mechanism for the nationwide health information network, and this imposes rule making. So why do we need rule making now? Well, we need to make sure that the users have trust in how their information is shared. We certainly want to know that the exchange is working effectively. We want to know that consumers and patients' expectations are met, if not exceeded. And we certainly want to know that it's being used for the outcomes that everyone around this table cares about. But there's some very pressing needs. Without governance, the NHIN Exchange, in fact, cannot expand and grow beyond specific categories of participants because these are currently limited by legal guidance that we have. This is not

a country club. This limitation is imposed on us by the requirements of rule making, and it wasn't intended to be that way. Again, we will evolve beyond that.

At the same time, we have new projects, new approaches that are evolving. They need —governance" with a small g. They actually need it with a capital G but we couldn't call it that, so we do need to move as rapidly as we can to get something in place. So rule making will certainly recognize the foundations that are in place, not only the legal foundations, but complementary mechanisms that exist, like the roles of …, etc. and the S&I Framework as you pointed out. That that is, in a way, a governance mechanism itself.

Setting the scope of rule making is the first step in who and what, discovering why and how, and what oversight and accountability is there. But you need to get concrete very fast. So we thought it would be useful to use what was called the HIE trust framework. I know it was presented to the Policy Committee by the NHIN work group. I don't know, was it presented here as well? Anyway, I'll just very briefly read these high level buckets that they came out with. These are attributes, these are not principles of governance but they're attributes. They're ways of bucketing what you might need.

So I'll read for the record that agreed upon business policy and legal requirements. That all participants will abide by an agreed upon set of rules, including but not necessarily limited to compliance with applicable law, and act in a way that protects the privacy and security of the information, and is in accordance with consumer and patient expectations. Transparent oversight. Oversight of exchange activities to assure compliance; oversight should be as transparent as possible. Enforcement and accountability; each participant must accept responsibility for its exchange activities and answer for adverse consequences. Identity assurance; all participants need to be confident that they're exchanging information with who they intend to, and that this is verified as part of the information exchange activity. Technical requirements; all participants agree to comply with some minimum technical requirements necessary for the exchange to occur reliably and securely.

Now again, it's premature to know whether these buckets will actually prove helpful in telling a story as we try to lay out governance as we move forward. No assumptions whatsoever, but for now they seem to be very helpful.

But first of all, there are some overarching questions of scope, and the biggest, of course, is whether patient or compliance should be optional, preferred, mandatory. Do we want an NHIN brand? Is there some foundational set of governance mechanisms that really need to be common across all forms of health information exchange? What do we need to do to ensure that the level of governance is appropriate to the risk or the benefit that's going to be there? How do we ensure that governance that we set in place in 2011 can be flexible enough to evolve over time, so that we don't have to go back to rule making each time? Should there be any … standards and services for the —outside" NHIN governance? When and how should we use rules and regulations, certification and accreditation … recognition of best practices, just watching the market place develop or any combination of the above?

So getting back then to some of the specific categories, under the business policy and legal requirements and expectations, a lot of these things do get at the privacy and security areas, so when should patient consent be required, and for what? Should it be at the level of populating the record locator service in the beginning to disclose … use THI? How granular should it be? The Tiger Team had a very interesting hearing yesterday that many of you I know were there, where it looked at the technical side of these choice issues and the granularity questions emerged there.

What requirements are necessary to assure data integrity and quality? Should requirements for consent and data use vary by exchange model, by inquiry, and look up known end points. How do you specify appropriate purposes for using exchange and using data, and how do you minimize and what should be the requirements for data minimization?

Oversight, of course, means the management and maintenance and supervision and monitoring of the trust relationship and the exchange activities. The nature of the oversight and the nature of the specific mechanisms might depend on the exchange model or the parties involved, and the needs that the partners themselves identify and the key questions that we have preliminarily identified here. Is there a role for federal or state oversight to monitor and address abuse of market behaviors? Is there need for a federal mechanism for information exchange organizations? What are the appropriate federal and state roles across a variety of areas? How can transparency and open processes be assured for setting the policies and requirements? And then how can transparency, oversight and accountability be assured? What are the specific mechanisms that you might want to use there?

So some of the key issues for enforcement and accountability. Every exchange partner needs to be accountable for its activities, and must be prepared to answer at multiple levels. It needs to be prepared to answer to individual subjects of the exchange information, other participants in the exchange, third parties that are providing enabling functions, certifiers or accreditors, and maybe even government entities in some cases. So if there's going to be a certification program for HIST or actual exchange participants, what are the key roles for those bodies? What are the requirements for certification accreditation? Are you going to set any limits on them? What are the types of enforcement and accountability measures that should be considered? And we have, of course, regulation and contractual requirements available to us.

So again, exchange partners won't exchange information with just anybody. They really need to know who they're exchanging with. So what should—I probably shouldn't say should there be. I think the answer is yes. But what should the identity assurance requirements be for provider access to clinical information for either access to the systems or the data itself. And what about for patients and consumers? And what about identity assurance for the participation itself in the exchange? And what are the mechanisms to validate the identity assurance processes and mechanisms?

I've lost my technical partner, as you'll see. Doug had to leave, and there really isn't a whole lot on this slide about technical requirements, but again, we certainly need to ensure interoperability, privacy and security, and we need measures that ensure that the data is received unaltered. We also know that noncompliance with the requirements for secure transport should prevent an exchange from occurring. So a few questions based on experience to date are, do we need additional testing and oversight to assure conformance with technical requirements? Right now there are official requirements for exchanging with federal agencies and government contracts through the exchange, but we have certification for use and other best practices. And what level of interoperability do we want to meet policy goals?

But again, I think I will end by perhaps going back to Cris Ross' question, because this is my last slide, and I will say again, we look to you for, at this stage, just asking the questions in the right way so we get the best input. I would also like to pick up something that was in an earlier slide, but let you know that we do intend to come back to you in September and ask you to have really some in depth opportunities to gather information and give us input. We had a preliminary conversation with Jonathan Perlin and John Halamka in our office, and we would like to suggest a joint, perhaps two day hearings to emphasize that the policies and the standards and technical issues, governance issues, are indeed entwined, and get

you to use your joint expertise in helping to frame those hearings and provide us with the more specific and concrete input that would actually shape the NPRM.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks very much. You've really outlined, I think, something that's encouraging to all of us, that there will be a unified governance process on all flavors of the NHIN. It will informed by public input, by input from this committee; ensure that technology and policy are appropriately coordinated and leading up to rule making. I think really, as I started in my remarks today, for everything there is a process, and I think so far, in our few hours this morning, we're now beginning to see the direction of the processes you're putting in place, so that's wonderful. Now let me open it up. Let's see, … was first on the button.

M
Thanks, Mary Jo, for outlining all of that. I'm not sure how to pose this as a question, but I think one of the challenges that we face in trying to move this forward is that we're trying to address issues of policy, process, for a number of related activities, and we tend to sort of just dump all this stuff in a bucket and call it the NHIN, when in fact we're doing many things with that information, with those services. We want to support, we aspire to support many things with that umbrella, if you will. And we've certainly found over the years it's very hard to get even small c consensus with providers and patients if we just throw 800 things on the table, because each of them have their micro issues. So the suggestion, or at least a thought is, are there particular pieces and uses, and I think the NHIN Direct discussion we had a bit ago is an example of that, where by identifying clearly use cases, that the governance and process might be different. There may not be just one that applies across everything. And while we want uniformity and consistency, we may hamper our ability to get to an answer if we try to solve everything in one large traunch of work.

Mary Jo Deering – ONC
Well, I don't believe I used uniformity, and I welcome your comment. Thank you very much. I would just punctuate that by saying we agree, and that will be, though, one of the challenges. It's where do you set the points of granularity? Given the fact that you don't want separate, clearly separate and distinct governance widely, but you want to be sensitive to the nuances of what actually needs to be done.

The other thing is, where are the urgent priorities? What can you build now, but again, knowing how slow the rule making process is, and yet knowing our urgency, as David has said, to begin to deliver, what can we deliver that is flexible enough to evolve over time without needing to return consistently to very cumbersome processes?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Thanks for your summary and the slides and great questions. It's like a reference that we should go back to and consult for, what are the questions that should be answered. But they all presume one thing which I noticed when you sited the single sentence in HITECH that refers to this mandate to create governance, that uses the definite article to refer to the NHIN; instead of an NHIN it refers to the NHIN. I'm just curious, what does that mean? Is there a formal definition for what the NHIN is that needs governance applied to it, or does the governance actually help define what it is?

Mary Jo Deering – ONC
I think it's a …. And again, this group has been party to the long evolution of the definition of the NHIN, and it is nothing more and nothing less than the set of standards, services and policies needed to securely exchange health information over the Internet. Now that said, it is certainly very, very large. I posed a question, are there any standards, services and policies that relate to some health information exchange that should be considered outside of governance? I think that's a question to ….

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Right. Because it would be certainly feasible, I mean, use the NHIN Direct for example, as a concrete example. It would be certainly feasible for anyone to adopt the standards, policies and technologies of NHIN Direct and use it completely legitimately in whatever way they wanted to. They're all open standards, and available, and as far as we know they're compliant with existing regulations. Does that mean anyone who uses that set of standards is the NHIN, or in this case, NHIN Direct? Or does it only mean if they put the name on it, the branding question?

Mary Jo Deering – ONC
I think those are all very good questions. I would point out that until rule making is final, nothing is final. And in fact, one of the things that John and others praised Arien for is the fact that there is a set of checkpoints, and those are not yet NHIN standards, services and policies. They are not yet. They won't be until they have gone through a checkpoint, of which this group is a major piece, to say yea or nay. So to date, they are not even NHIN standards, services and policies. But it is fully expected that there will be some that emerge. But again, you helped frame the question at the level that it needs to be framed.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I think this set of slides talked a lot about the governance process, and a lot of the questions are trying to frame the process, the scope, but one element that I didn't seen described is the structure of governance. Is the question what should be—perhaps that is part of the overall question of the … what should be the structure of governance? Not so much the process of should it cover this or that? My assumption is that it covers everything about NHIN, perhaps, and that's one of the questions, too, NHIN Direct and NHIN Connect and NHIN Exchange. It seems like we should create NHIN everywhere. But it seems like the key element that is missing in this approach is what should be the structure itself of governance. If there is a structure to be defined, where there is an organization, where there is a body, a whatever it is or it could be, I think it needs to be explained or defined. I think that would be one of the questions to ask about if there's going to be an … understand what would people expect to see as a structure of governance.

The second comment I would make is emphasizing the relationship of NHIN and this governance structure to the 50+ HIEs that are evolving and expanding and growing and formalizing. I think they are going to have a very important expectation about what this is all going to do to how they are approaching their own internal governance in their own HIE. So I think emphasizing or expanding how this governance approach relates to the evolving state HIEs will be important.

Mary Jo Deering – ONC
I'd like to comment on your first thought, but I neglected to introduce my colleague, Steve Posnack, who in Jodi Daniels' absence as a new mom is, indeed, acting in Jodi's place, and of course, you all know him, as I introduced him on Friday as Mr. Rulemaker. So he will be shepherding this until it gets processed on through, and can certainly address those issues.

I had a question about your question about structure. It sounded to me like it assumes some singular something. Is that a correct interpretation of your question?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
No. It doesn't assume any—it just assumes that there will be a structure. My question really goes to the question that people will have, which is, so yes, we understand this whole process, or we can provide you input about this process, but who is governance? And who might be many different groups, many different things. But the important thing is to identify the structure of it. I mean, all these questions point to

the process, and how things would be done, but again, I'm not advocating at all any particular singular structure or a particular singular entity or anything like that. I think the question is going to come out as, so who is the governance?

Mary Jo Deering – ONC
I think that is excellent, and thank you for reminding us. Actually, we have multiple drafts of white papers that we've circulated internally, and one of them always would have as one of the initial assumptions that there shall be no single uber entity that oversees all aspects. But what you are reminding us is that we need to get to the point where we can say, assuming plurality, what is that plurality and what does it look like?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I think the other thing to point, too, that you've alluded to, Walter, is that it maybe more than just whos? It could be whats and hows. So how something gets done in a compliant way within NIHN as an abstract concept; there could be baselines that could be set for participants. I mean, we're not presupposing anything in terms of what governance may include.

M
Thanks, Jim Walker. I want to propose that in this case, and in any other case, when we start talking about whether compliance is optional, preferred or mandatory, that we hold ourselves to the standard of documenting what the cost to resource constrained organizations of compliance will be before we make it either preferred or mandatory.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Salient point. Carol Diamond.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Mary Jo, thank you for those very thoughtful questions. It was fun to listen to your sharp mind. I was going to just make a suggestion, building on some of the comments we got here. I think one way to get more precise input, and I'm harkening back also to the earlier process, one way to get more precise input is to provide more precise constraints in the way you ask these questions. Some of these questions might be answered four different ways, depending on which element of NHIN the person might have in their mind when they're trying to give you input. And in particular, I would also triage those elements of "governance" and I like the idea of plurality, because I don't think there's an uber issue. But I like the idea of triaging those elements that are pressing from a time standpoint, where you might be able to go into more specificity about the objective, about what's necessary, about the timeframe as a constraint, and then you might get more specific input that is mindful of, well this has to be in place by such and such a date, and it's necessary to comment on these specific elements of the subset of issues that are NHIN. I think that helps people try to provide input in a way that is more useful.

Jonathan Perlin – Hospital Corporation of America – CMO & President
So Wes, final comment and then we break for lunch.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Oh my god, it's déjà vu all over again. In the spirit of what Carol was saying, there are so many degrees of freedom in these questions that you may want to consider some approach that is almost like playing out options or something like that, some way to say, not that we are telegraphing any intension that this would be a regulations, but if it were, how would it play out, and several alternatives. Something like that, just to try to give something tangible to react to.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, we are 15 minutes behind, but I recognize trying to compress lunch into 29 minutes flat is going to be very challenging in this setting, so let us return at 12:45. I think we will catch up. I'm looking at the afternoon and there are somewhat less controversial topics in the afternoon; important, but less controversial. So thanks very, very much for the rich discussion, everybody, and thanks very much Mary Jo and Steve, and we will see you at 12:45 promptly.

(Party breaks for lunch.)

Judy Sparrow – Office of the National Coordinator – Executive Director
I think we're ready to begin, if everybody would please take their seats. Is the public line open, operator?

Operator
Yes it is.

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay. Thank you. I'll turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, thank you very much and welcome back, everybody. I really appreciated the discussion of governance. It just reminded me that democracy is inherently messy and it took me back to a great quote by Winston Churchill, —Democracy is the very worst form of government except for all of the others." That's where we are is that this is open, as it should be, process that I think is just terrific input about the utility of the meaning of consensus, the utility of policy and in forming criteria and driving towards outcomes, as ONC is charged, in the specified time.

We may do a little rearranging in this afternoon's schedule. So, Deven, with your permission, we'll go to you after Janet Corrigan's update on Clinical Quality and so without further ado, let's go to Janet Corrigan. You were expecting Floyd? Do you want to wait?

Janet Corrigan – National Quality Forum – President & CEO
I'm expecting Floyd. If you could flip it with ….

Jonathan Perlin – Hospital Corporation of America – CMO & President
I'd be happy to. Deven, thank you very much for volunteering.

Deven McGraw - Center for Democracy & Technology – Director
Flexibility is wonderful. No problem. Plus, it gave me a place to eat my snack. All right, so I'm here to give you an update from the relatively newly formed Privacy and Security Tiger Team.

What is the Tiger Team? First of all, we did blatantly steal the Tiger Team name from the HITSP Tiger Team that was established, so all credit is due. The substance of what we're doing is not the same, but the notion of sort of quickly responding to some urgent needs is absolutely appropriate. It has both Policy Committee and Standards Committee members on it. There are a number of folks around the table who are participating. The idea is to resolve some issues that have some degree of time sensitivity associated with them, but we are resolving the policy issues, but we're trying to do so in that iterative way that takes into account what the technology can or cannot do so that inevitably we have a set of policy recommendations that have technology in mind. So the idea is then you're ideally that much further forward and well informed in the set of policy recommendations that you make.

Most of the members are drawn from the Policy and Standards Committee. We also have representation from NCVHS, so essentially, the existing Privacy and Security Workgroups of each of the FACA bodies are not dissolved, but on a bit of hiatus. That has been the source of some of our outside expertise, quite frankly, which we hope as we go sort of from topic to topic as a Tiger Team that we can still engage those folks in providing us with input on particular issues where they have expertise as they arise.

Again, the hope is that this sort of intensive process; and we have had meetings as often as two times a week for three hours at a time, so it is quite intense; that we'll be able to get through some good, solid, baseline policies that are needed to be decided over the summer and then go back to the more larger workgroup structure around the fall. It's not entirely clear when that will happen, but we don't see this sort of intensive process as lasting for longer than the summer in part because I think people will cry uncle at some point as it really is quite the process.

So here's the list of team members. You'll recognize a number of the names on there. This is the proposed schedule of topics that we put before the Policy Committee at their meeting last Friday, but to be honest, this is going to be iterated in a lot more detail. These were just sort of general guideposts that we started with, handling more directed exchange in June. We had a Consumer Choice Technology Hearing on June 29th, which is actually something, which the preparations for that began well before we formed the Tiger Team, but we had it yesterday and we can talk a little bit about that.

In July we want to continue to deal with policy issues related to directed models of exchange and I'll say what I mean by that in a second; also look at what are some of the other exchange models that are out there; deal with issues of consent within a context of other policy issues, ideally. That's an issue that cannot really be meaningfully resolved in a vacuum, but with each policy committee meeting through the summer the idea is to have a concrete set of recommendations for the Committee to hopefully adopt; that's the idea, so that we are making progress on these issues on a steady basis through the summer.

We've got governance slotted for August, but as you saw in Mary Jo's presentation, essentially some of the substantive issues that are part of governance are at the heart of really what we're doing throughout the summer, so when we have governance slotted in August we're really sort of talking about mechanisms, structural process issues that Walter raised earlier, as opposed to the what, what are the set of rules. I mean essentially what we're doing all summer is thinking about the rules, how you would enforce those rules and through what level of accountability to the extent that we may be making recommendations on those all along, quite frankly, but we just put a placeholder in for some over arching governance issues that we might want to deal with in the month of August. Again, we are continuing to refine this so that there's a little bit more detail to it.

So where we started actually was with a couple of questions that were keyed up to us by the NHIN Direct Team, but there was a desire expressed on the part of my Co-Chair, Paul Egerman, which I agreed with, which is not to confine necessarily the recommendations that we would make about direct exchange models, which we think about as transporting patient data from one provider to another where you have both providers involved in the care of the patient; we call that directed exchange model; versus saying that we were making policy per se that was just exclusive to NHIN Direct. I think we saw NHIN Direct as being a potential model of directed exchange, but that directed exchange might look different, again, depending on what you were dealing with, but with the common denominator being the sending of data by the provider who is the data holder to a recipient provider with both providers essentially having a treatment relationship with the patient, sort of a more basic level model.

We had two questions teed up to us specifically that needed to be addressed. One is what are sort of some basic policies or policy guardrails for handling the message that goes from one provider to another

in a directed exchange model. The second question was who is responsible for establishing the trust. Who holds the trust is another way to think about this when messages are sent. We had to start with thinking through even in a directed exchange model there is some variety about what that looks like and we just sort of sketched out four categories; one being where there's no ~~-in~~termediary" involved. There is a direct exchange from the message originator to the recipient.

The second level would be yes there's an intermediary, but all that intermediary is doing is essentially routing from point A to point B and it doesn't have access to any unencrypted PHI, which I think you all know is protected health information, identifiable at the patient level. So the message body is encrypted and the intermediary can't access that. C is yes the intermediary has some access to PHI that's not encrypted, but there's no messaging or changing of the data in the message body. Then in D the intermediary would open the message and change the message body.

Now, I think there's probably, I'm sure, some gradations of models in between and probably not universal agreement about whether one particular directed exchange model fits in one model or the other. To me that's not as important as thinking about the level of exposure of patient level data in those models, so if you think about it's a graduation from a model A, where there's essentially no one in the middle who see patient level data; it goes directly from the one provider to another to B, where yes, there's something in the middle, but the middle person, the middle man, the intermediary, however you want to refer to them, in fact, it's almost the same as model A, because they can't access the patient level data and then you sort of go up the food chain. I mean I call it a food chain; one could also conceive of it as a risk chain. In fact, that's essentially what we said, which is that unencrypted PHI exposure to an intermediary does raise privacy concerns and so certainly, you have fewer concerns that are raised when you have no unencrypted PHI exposed between the two end points.

The other models, where there is intermediary access to some unencrypted PHI do introduce some privacy and safety concerns and you need to have policies that deal with the intermediary's use of this data, particularly when you talk about re-use and retention beyond the purposes for which the intermediary was interacting with the data. We are, as a Tiger Team, going to be taking an additional look at again where there are intermediaries used, what sorts of policies will need to be in place. I think a lot of folks think about, recognize that in this type of arrangement there is a business associate agreement that's likely to be in place and that's absolutely true, but that only answers the question of the mechanism for creating a set of policy expectations that can then be enforced.

It doesn't actually tell you what are the set of expectations that you would require an intermediary to agree to in terms of the re-use and retention of any data that they might be exposed to in performing a function. Intermediaries who also are collecting and retaining audit trails that might in fact, in the audit trail itself, have exposed PHI, the same sorts of policy constraints that deal with the intermediary access to the message content ought to apply also to an audit trail if, in fact, that audit trail actually exposes identifiable data.

Then we also recognize that when you have the sort of more, we might call them, robust models for lack of a better word, but models where you have intermediaries performing a range of services that might involve data manipulation there are some other issues that are not necessarily privacy related, but could be patient safety related about the accuracy of what's happening to the data. So if it's, for example, an intermediary performing a vital function of transposing data that's in unstructured content into structured content or manipulating data in a way to present it to the provider on the other side that it's in a format that that provider's system understands there needs to be some level of confidence and assurance that, in fact, the data hasn't been inappropriately massaged or manipulated along the way. So that ought to be part of those contractual arrangements as well.

Before I leave this slide I want to make sure that I correct what I think was a misinterpretation of what we were trying to say that might have occurred at the Policy Committee. We did not, as a Tiger Team, say that intermediaries are bad and that we should avoid using intermediaries. We recognize, and I recognize, as the privacy advocate, there is a valuable service to be provided by an intermediary in the middle and the transforming of data from unstructured content into the required standard or structured data is one area that you can clearly see.

Another area in NHIN Direct, for example, is who is going to put the encryption around the content in order to facilitate the transport in a way that it can't be intercepted in the middle. Well, you can't expect our small physician practices to be able to manage their own PKI. They're going to need to need to hire somebody to help them do that. So it was not intended to be some sort of pronouncement that thou shalt not use intermediaries. It was really intended to be a recognition that there is risk when data is exposed in the transport and the model that's chosen for a directed exchange needs to be – so to the extent that you've got an intermediary that's needed in order to effectuate that transport the idea is that if that intermediary is merely performing a routing function that the data would not be exposed to them in order for them to make the route from point A to point B. If they are needed though to perform a function in order to facilitate that transport, such as the addition of the encryption layer, you know, absolutely. We weren't saying that shouldn't be done, but the fact that you are introducing an intermediary that has access to data by performing that function, there's a need for some policy rules that should build around that.

Having said that, on the other hand, we also don't want to have a situation where any model is acceptable because ultimately we'll just create some policies around how the intermediaries will be using the data that they might be gathering from point A to point B. If the data doesn't need to be collected by the intermediary for any legitimate purpose, it shouldn't be. So the default is not any model will do as long as we have some rules around what the intermediaries can and can't do with data, because ultimately, if there's a legitimate purpose that the intermediary is serving and they have a need for data for that purpose they're going to have a need for data for that purpose and there ought to be some parameters around that. On the other hand, if that access to data isn't needed in order to perform the function we actually should define the policy in a way that limits that access to data because that is far safer and far easier to enforce than after the fact trying to put some rules around what you can do with that data once you have it. I hope that makes sense, but I'm happy to answer questions about it.

The other question about who holds the trust was more a matter of is this a centralized, single authority or are we talking about something that's decentralized. Ultimately, it is really the provider who has the responsibility for maintaining the privacy and security of a patient's record. That's really the standard in HIPAA, so to the extent that you have a provider, who is sending data to another provider, it is ultimately her responsibility to know that where she is sending it is to the right provider. But we also fully understand that for a lot of providers they're going to need some help in making that decision and so they should be able to delegate that authority to whether it's an authorized credentialing service, a HISP, an intermediary, whatever you want to call it. There is a role for a service provider to play to help a provider to fulfill that function.

Now, in order to assist physicians and hospitals in making the decision about who is the right credentialing authority, what's the right HISP for me to trust, obviously, we need standards in place. We think the federal government has a role in establishing and enforcing clear requirements and policies about this credentialing process, including the identification and authentication pieces. But that doesn't say that there's not a role for state governments to play as well. We know we live in a federal system here, and so there is definitely a role for state government to play as well.

Now, that was the sum total of the recommendations that were consensus recommendations of the Tiger Team above the line. We did have a discussion, again, stepping back for a second, the recommendations that I just talked about were to directed exchange, which NHIN Direct and what the technical team at NHIN Direct has been working on is just one element of that.

On our recent call there was a desire by most of those who were participating on the call; it was a clear call consensus, quite frankly; that we ought to say something more specific about NHIN Direct as a model of directed exchange and that in the NHIN Direct, and we're really talking about the transport layer, from point A to point B, it does not need to have access to unencrypted PHI. I think this is where the source of the confusion came out, because after the call there were a number of concerns raised by some of the team members, who are not able to be on, that, number one, they were uncomfortable with creating policy that was just about NHIN Direct. Some of us were not so uncomfortable, but others were, so we went back to the general directed exchange recommendations that we had come up with.

Having said that, I actually believe that the recommendation on NHIN Direct where you're talking about point A to point B in a mere transport functionality is completely consistent with the recommendation that we had earlier. I'm completely understanding the role that intermediaries can play in providing a valuable set of services to providers who are seeking to exchange data, but at the level of transport from point A to point B does there need to be data exposed to an intermediary in that context. Again, I think it's completely consistent and so to the extent that this was an extension of our recommendations to a particular set of circumstances, I personally don't see any inconsistency there, but we ran out of time on our last call. We didn't have another call to try to resolve the questions that arose after the fact and we may, in fact, try to do that in subsequent calls, but again, since I don't see an inconsistency there with the recommendations that, in fact, did get endorsed by the Policy Committee, it doesn't feel terribly consequential, but I wanted to give you the same set of slides that the Policy Committee got.

The second piece, which we're definitely going to do some more work on, is that there is a role for transparency to patients about even directed exchange where you're not using a sort of HIE or RHIO in the middle. At a minimum, patients need to understand what's happening with their data when it's going from one provider to the other, that it's electronically being exchanged. The reason why this didn't move into the other category of a concrete consensus recommendation is in part because we've got some work to do about when we say transparency what exactly do we think needs to be disclosed to patients in circumstances where you do have a range of service providers or intermediaries providing value adds to providers exchanging data and what would that look like. So we're going to do some more work on there, but suffice it to say transparency is a high priority among the members of the team.

So we can move into questions, but I will just say in terms of our hearing yesterday, it was about the state of the technology for managing patient consent to the use and exchange of data and the policy side of the house needing to get a full understanding of sort of where the state of the technology was before we could move to the piece of thinking about what the policy ought to be. It was long. It was 8:00 to 5:30, so for those of you who were not able to be there, you missed it. For those of you who were, including we tapped Jim Walker to be on a reactor panel and he did a terrific job, I think we got some very good – I think we got a really good, realistic look at what's out there, which is both that there are definitely some developments in the technology that I think are important in this space, but there are also some limits to its scalability and how it can be applied. So I'll just say that. That is we have not spoken about this as a Tiger Team, so that's my own personal assessment of what I saw yesterday.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much, Deven McGraw, for a terrific summary of the work of the Tiger Team. I want to note we're joined by Aneesh Chopra, who will report on the work that he's been doing as well. As you mentioned earlier in your presentation, a number of the members of the Standards Committee are also members of the Tiger Team; Carol and Dixie and David and Wes in particular, so we particularly invite any comments—

Deven McGraw - Center for Democracy & Technology – Director
They're probably correcting me.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Any comments on things just to bring up? John, you wanted to make a comment.

John Halamka – Harvard Medical School – Chief Information Officer
Right. It's very brief. You have the categories of message handling and I recognize the Tiger Team worked quite hard on putting together this framework. As I run an HIE, I will tell you I don't actually think of the HIE as an intermediary. I think of it as a service provider, of which there are a set of services, such as transport, that need not inspect the package; conformance testing, "Well, if you want to enroll in that particular service then we do need to open the package and check it for conformance," translation of one standard to the other. So in thinking about your work forward, a friendly amendment, I wonder if instead of saying categories of message handling you might think of services that might be provided.

Deven McGraw - Center for Democracy & Technology – Director
That's fair. Since we keep getting into disagreements about who's an intermediary and who's not that might help us get over the hump.

John Halamka – Harvard Medical School – Chief Information Officer
What I take away from that a very practical level is that the activities of an ... I mean nothing is mutually exclusive in terms of how they handle the information, so that recommendation, I think, has a lot of utility and practical application.

NEHIN, New England Health Exchange Network, today does transport and pure routing doesn't require that we inspect a package, but it turns out our members in 1997, when we first put this together, actually weren't very good at assembling content packages. They said, "Please inspect this to make sure that we're conformant with the standard," and so they elected by opting in for us to open the package. I'll tell you, in 2010 we actually don't really need to do that anymore because, at least at this point, X12 4010 is pretty well implemented in a consistent fashion. Now, when 5010 starts I'm sure they'll want us to check it again.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, John. We'll continue around the table with David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Deven, you were in the back of the room this morning, right?

Deven McGraw - Center for Democracy & Technology – Director
Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I thought I saw you back there.

Deven McGraw - Center for Democracy & Technology – Director
Yes.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
For those of us who kept badgering the rest of the Tiger Team about the NHIN Direct, I hope you, from this morning's context, understood why we felt that pressure to seek that advice. I mean there really was a lot of pressure to get advice from the Tiger Team—

Deven McGraw - Center for Democracy & Technology – Director
Yes. No. Right. Well, I wasn't trying to suggest that it was. I actually thought that it was helpful to be that specific—

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes.

Deven McGraw - Center for Democracy & Technology – Director
But do you agree with me that it's not at all inconsistent with the –

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I totally agree.

Deven McGraw - Center for Democracy & Technology – Director
Okay.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I just know there was some tension about whether we should even be talking about NHIN Direct.

Deven McGraw - Center for Democracy & Technology – Director
I know.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
If you heard this morning's conversation, we had no choice but to talk about NHIN Direct because we—

Deven McGraw - Center for Democracy & Technology – Director
Right. Right. No. I get it. I get it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
There is a lot of pressure.

Deven McGraw - Center for Democracy & Technology – Director
I get it. It's what's on the table. It's like ignoring the elephant in the room, right?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
It all worked out. Then the second, maybe slightly – Tiger we had that debate too. Which animal was it? We were jaguars or cheetahs or what. I'll save my second comment for later some time. Never mind. I'll stop. It was going to be cynical and maybe we don't need cynicism.

Deven McGraw - Center for Democracy & Technology – Director
No cynicism. Park that at the door.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay. With that we'll go to Marc Overhage.

Marc Overhage – Regenstrief – Director
Thank you very much. Thank you, Deven. You didn't hear Wes over here making comments about the level of technologic sophistication you brought to this discussion, but it's really true. Thank you.

Deven McGraw - Center for Democracy & Technology – Director
Oh, he was being sarcastic, wasn't he?

Marc Overhage – Regenstrief – Director
No, he was not. I can tell when he's being sarcastic because he's usually talking about me. I did have two observations or clarifications that I wondered if you could help me with. One is you talked about directed exchange and I think I heard you say that the domain you were thinking about was restricted to treatment uses—

Deven McGraw - Center for Democracy & Technology – Director
Yes.

Marc Overhage – Regenstrief – Director
Not quality measurement. Not public health reporting. Not drug safety. Treatment.

Deven McGraw - Center for Democracy & Technology – Director
Not yet. Yes. Treatment only.

Marc Overhage – Regenstrief – Director
I just wanted to make sure I understood that correctly. It gets back to the comment I made in the last session about I think it's great, because you've got to draw some boxes around this stuff to be able to get anywhere.

The second thing; and I think you said this also, but I just want to make sure I'm hearing this right; is one of the challenges in the thinking, it's sort of a simple, mental model when you think about Doctor X and he's got sort of his encrypted e-mail server or whatever and it's set up in his practice and his son is smart enough to do it and is on the payroll and is bonded and certified and all of that good stuff. Doctor Y has the same setup and then exchange, that's a simple model to see.

As soon as you start saying, "Well, but now he's got software as a service, EMR provided by somebody in India," that's a little extreme. We'll just leave it in .... But he's got this hosted EMR and I mean I think it's easy to imagine end point to end point the data being encrypted and PHI being completely invisible on the wire, if you will. The question is where does the wire start. I think you used the term boundary around the end points. And so to some extent; I don't want to say this too strongly, but the notion of an intermediary is a bit of a fiction in that there's always an intermediary. That's not bad. I mean it's a valid point and you do have to worry about it. You're almost always going to have an intermediary I think. Even in an organization like Kaiser or something you may well choose to contract a service like this out to somebody.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Marc Overhage – Regenstrief – Director

I mean not that they couldn't do it themselves, but it may make more sense for Cisco to deliver that. By the way, there's a press release today—No. But it may make sense for somebody like that to do that service and have it. So I think there's almost always going to be an intermediary and so while it's a really simple notion I think what makes me nervous about that is only that you made a point about A and B is the way directed exchange ought to happen. Yet, I think it's always going to look more like C and D in reality because I'm going to have to hire somebody to do it. Then your points are perfectly spot on. We then need the appropriate policy and business associate agreements and what does that mean in place between whoever it is.

Deven McGraw - Center for Democracy & Technology – Director
Right.

Marc Overhage – Regenstrief – Director
Because I just don't think we're ever going to see that pure picture of I've got my iron port e-mail server and I set it up and manage it myself.

M
....

Deven McGraw - Center for Democracy & Technology – Director
Right. Well, yes. I mean I don't disagree with you. Again, the benefit that I have from what my colleague Paul Egerman had in presenting to the Policy Committee is that I was able to digest what the reaction was, which was to suggest that we, as a Tiger Team, were anti-intermediary, which is not true.

But what we were really responding to is where you've got, again, a simple routing transaction taking place is there a need? Where is the room from a policy standpoint for a model that exposes data in the middle where there isn't a need to in order to perform that function? If you need to expose the data in order to perform a valid function, such as the ones that you said, then absolutely, that makes sense. We're not suggesting that providers would need to do it all themselves. They would find a lot of valuable services that an entity, a service provider could do. But whether that, consistent with the notion that always that function should take place with the least amount of data that is needed in order to perform it; if all that's happening is routing that exposure shouldn't be there.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go on to Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thank you. Not to be cynical, but whenever a speaker says about eight times I don't think these two points are inconsistent I start looking for the inconsistency.

Deven McGraw - Center for Democracy & Technology – Director
Okay.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I was not able to listen to the Policy Committee meeting, but I do understand. Was there an agreement to modify recommendation there? Is that how it went?

Deven McGraw - Center for Democracy & Technology – Director
What was struck was a simple line in the second bullet. The second bullet read as it says and it had an additional sentence that said, ~~"~~ONC should encourage the use of these models."

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. So that in essence, in the relationship between the Policy Committee and the Workgroup, that would be taken as marching orders in essence. Is that right?

Deven McGraw - Center for Democracy & Technology – Director
Well, again, they took that statement to mean to not fully recognize the value that service providers bring to the table versus, instead, the way that I understood the statement to be and the reason why I thought, why we put it in the recommendations to begin with was the basic point that I've been trying to make; that what you're talking about, a basic transport of data from point A to point B you shouldn't need to expose data in the middle. That's what was intended by that, but the Committee read that statement to mean it was sort of this anti-additional services approach and there is such value in those additional services that that was sort of silly.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. Thank you. So, speaking to Marc's point about the frequency and level of intermediaries and the level of intermediariness, if that were a word, some of the examples you gave; and I stress only some; would be covered by business associate agreements under HIPAA. So, for example, an EMR vendor signs a business associate agreement. I would hope that we would seek to do two things. One, assure that there is some approach for all intermediaries that have exposure to the data. I think your point about a business associate agreement being an instrument of enforcing policy rather than a statement of policy is correct. I think that some people, however, who say they will have a business associate agreement are really thinking of the specifics of the requirements in HIPAA, which are essentially to say the business associate shares the risk and, as of last year, the penalties that are involved. So we might want to consider the statements about a business associate agreement as a metaphor for a statement of proposed policy. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you. Walter Suarez.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I have a couple of comments/questions. I think, and this is probably emphasizing some of the points that have been made, but this reminded me of the discussion that we had many years ago with HIPAA transactions and who is subject to what and who is really a covered entity and where does a transaction ... because we, in many respects, went through this same analysis of intermediaries and who is doing it. Pretty much, in every transaction not only there is one intermediary; there is probably more than just one. Not only that, some of the intermediaries are you in your category B and some are in C and some are in D.

At the same time, in the exact same transaction, I remember we even had a discussion about back in the days I lived in Minnesota and U.S. West was a telecommunication company, so U.S. West was a routing vendor provider for exchanging data between two providers in the state because everybody was leasing lines from U.S. West and they were moving the data, if you will. So even in those sorts of direct exchanges there was that type of intermediary.

Now, in addition to that, sometimes there was, of course, in the administrative transaction side and probably too in some of the clinical transactions you need a translator and then you need a clearinghouse and then you need another clearinghouse at the other end and another translator. So you end up in a single transaction dealing with five or six different intermediaries, some of them not doing anything but just routing, not touching the data, but just moving it, some of them having to open the envelope, if you

will, and some of them having to actually translate and modify not the content in the sense of the data itself, but content in the sense of the formatting. So I think it would be helpful to, while these categories are very helpful to begin to understand the complexity, I think it's going to be necessary to, in the recommendations, consider that there is always the issue of multiple intermediaries playing multiple roles in a single transaction and it is almost all of the time.

I would even, in the recommendations on the last one ... intermediary for model C and D require contractual agreement, I think even the B intermediaries in many cases, organizations do establish contractual agreements and go into even business associate agreements because of concerns of they're going to have the data even though it might be encrypted or it might be de-identified. They're going to have PHI somehow and we're going to have to give it to them, encrypted or not. So I think it would be appropriate probably just to avoid any perception that model B we don't need contractual agreements. It would be helpful to expand it to that.

Then lastly, to the point about establishing exchange credentials, I think this is a very interesting area because I'm not sure if you have seen this yet, but about five days ago the Department of Homeland Security released something called a National Strategy for Trusted Identities in Cyber Space. The very first goal was to establish an identity ecosystem framework to be used in cyber space to establish appropriate identities. One of their topic examples is accessing health records and the whole electronic health record approach. So I think it will be important to probably look at sort of the larger perspective of how the federal government is looking at this from a multi-agency, multi-industry perspective. I think there are a lot of good things in that framework that they're looking at developing. I think the healthcare industry would need to fit into that model and provide probably some of the leading elements in their development. I just wanted to raise that ....

Deven McGraw - Center for Democracy & Technology – Director
Yes. No. I had seen that. That came out after this. But yes, I agree. Your points are very helpful. Thank you, Walter.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay. Well, let's thank Deven McGraw. Thank you very much. We'll look forward to continuing a close working relationship. I appreciate the good discussion around that.

Deven McGraw - Center for Democracy & Technology – Director
Thank you for the opportunity.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Really, it is part of a ... theme today of creating a trust fabric that makes all of this work and a big part of making it work is to really facilitate the ... value of care patients, the value of healthcare. Aneesh Chopra will be speaking about a critically important entry point into that equation and that is the work of the Enrollment Workgroup. I appreciate Aneesh being here.

Aneesh Chopra – White House – CTO
Let me close my lunch.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We'll do a little switch here. While Aneesh is going to the podium I want to thank and acknowledge John Derr ... reports he submitted to Judy Sparrow for the record of this Committee, A Roadmap for Health IT and Long-Term and Post-Acute Care, which is really a consensus document of a number of people and he wants to bring it to our attention in our deliberations. Indeed, the Committee will have this next time

and hopefully post a link to the PDF of it. We thank John Derr for the work, the tremendous consensus work around that that I think seeks to anticipate a lot of the direction, but also be responsive to that direction. Thank you, John. Aneesh?

Aneesh Chopra – White House – CTO

First of all, my apologies for having been missing for a couple of these sessions, I look forward to this meeting more so than many others on my list and so, forgive me for my absence. I have a very brief set of slides that I'd like to share and then I look forward to having a big dialogue about how this all will work. I want to particularly thank Anne and others, I think, who are on the Committee. I think actually Anne may be the only one who's physically— Chris. How could you miss Chris? He's taller than all. All right. Here we go.

You all remember the context: Health reform. Let's simplify the process to enroll people as they are welcomed into our 2014 environment. How should we set the standards framework so that we can achieve the goals of simplification for the applicants over the course of this process? There are a number of voices that we've brought to the table. First and foremost, it's a joint venture between the Policy and Standards Committees, as you know, but also, if you take a look at the list it's a pretty interesting mix of Web services folks, state and local folks, those in the industry traditionally in providing social services, enrollment services, as well as stakeholders in the broader ecosystem; a reasonably thoughtful mix of people that actually makes the meetings a lot of fun. Almost as fun as the Standard Committee, but maybe just a little bit more fun. We also have a number of federal players at the table, some usual suspects and some new faces that haven't been part of the health IT debate historically.

This is the charge. You remember this. As always, our homework assignments sort of feel odd. We have to produce recommendations on standards before the policy framework is finalized for how the environment will work. But we are committed to ensuring that what we do actually is in service to the potential policy options that are available. You'll hear about that in a minute. The bottom-line is that we will come back to this committee over the course of the coming months because we have to issue recommendations to the secretary by September and that means another fun summer.

Our homework specifically, specifically is to inventory the standards that are already in use, acknowledge that there may be gaps between what's in use today and what's required as we look forward to 2014, and to suggest candidate standards that either should be encouraged or a process to close any gaps in the following dimensions: One, electronic matching across state and federal data; the retrieval and submission of electronic documentation for verification. A key aspect of health reform is to verify income, citizenship, a number of other dimensions, so how we actually run those verification transactions will be critical. The re-use of this information, so if you are contributing or communicating that you'd like to have access to a high risk pool, but you later have a change in circumstances and you want to qualify for food stamps, how might you think of re-usability of that information so that you can have a simplified experience. The capability for individuals to retain their information in some form or fashion and, obviously, some creative options on notification of eligibility; instead of waiting for you to come to the mountaintop, how might the mountaintop actually communicate with you when there are opportunities in the ... specifically ... areas like texting and phone and other modalities in addition to in-person and on-line services.

The deliverables: We are in the midst of a process to inventory current standards based, data exchange activities that are in use to enroll people in health and human services programs. We are going to hopefully recommend a set of candidate standards for data elements and messaging that is irrespective of how. Is there going to be a single portal to rule all portals? Is there going to be lots of state portals? Are there going to be local activities, federal, state, insurance exchange only, insurance exchange plus

social burden? As the policy community engages on all of those topics, at the end of the day there are some basic data elements that we need to capture and use for verification and other purposes. Can we understand at the atomic level what are the data elements necessary and the messaging standards that would be appropriate for any and all of those scenarios?

Then obviously, as I mentioned earlier, the process steps to fill in the gaps so that we have essentially this rapid-fire turnaround of identifying the need and building working prototypes, rough consensus, running .... We've been down that road before. Some examples: Core data elements would include your name, your address, your residency and so forth.

The messaging standards around how do you check the eligibility and enrollment status, how do you match a consumer across systems, how can you send information in packages that would include your income, your employment status and your citizenship. That's been validated perhaps, mostly by a federal agency. How do we communicate that enrollment information, both to the individual, who has now successfully been awarded the enrollment, as well as to the entity that will be doing the work on their behalf, in this case, the health plans in many cases? Obviously, from the context of the conversation I walked into, what are the thoughtful ways in which we can ensure privacy and security in the transport layer in the authentication conversation?

The requirements that we're working on here are to conceptualize standards that are useful and, as I said, across a whole range of architectures. As I said to you earlier, there is this notion of a consumer portal, which we added for this testimony. I wanted to highlight the multiple modalities of the lower case P portal, not capital P portal .... This is lower case P, so it's on-line, mail or phone based systems. There are obviously a number of states that have gone through a comprehensive eligibility modernization program across a range of health and human services programs. There are proposed state and federal exchanges that will be a part of the 2014 environment. So we have put ourselves in some constraints so that the work doesn't stray too far from its core mission and that core mission is to ensure, as the Policy Committee had done, the following principles of consumer as the center, making the enrollment process less burdensome and simple. Enter the information once and reuse where necessary and obviously, you make it simpler for the consumers, who can focus on lots of programs with particular emphasis on 2014.

Here in the Standards Committee we've obviously had our set of principles as well, keeping things simple, not letting the ... good enough, making sure that we keep implementation costs as low as possible. I just want you all to know I will be focused like a hawk on bullet number three. That could be capital three, the bullet to rule them all in my mind. This is not about an unfunded mandate to various state, local and other ..., who can't afford all of the IT that's going to be necessary to do something at the end of the day that's in the best interest of people, so we've got to engineer to the constraint. I heard a term that I will now use moving forward, affordable engineering. That will be my guiding principle on bullet three. Then, obviously, not to create a one-size-fits-all standard, again, this is not about imposing some big technical mandate on all stakeholders.

We have a base use case that I must highlight in capital letters is under discussion. This is not finalized, but this was introduced to the working group as early as this week, Monday. I don't even know what day it is. Monday. I'm going to highlight it and then I'll have a graphic for it and then I'll be quiet. It has the following dimensions: The base use case to evaluate would be, one, how do we identify the available services for which the individual may be eligible. Two: How might we conduct any initial screening and enrollment checks?

Three: In the context of messaging, how do we verify the information? So if I claim that I made $24,000 last year what mechanisms are there to validate or verify that data? How do I determine eligibility or

forward the eligibility packet, if you will, that package information just referenced, to its final determination site or agency or whatever the case may be? How and what's the thoughtful model for storing and reusing eligibility information?

This would support a number of different policy scenarios. One scenario is a deep dive just on the health insurance exchange environment. That insurance exchange environment we heard in testimony is to screen for the income eligible groups that are called for in the legislation specifically between Medicaid, the Children's Health Program, the Exchange. I might add to that the high risk pool and how might we communicate back and forth with Medicaid in particular.

The second scenario is kind of building a little bit of a human services wrapper, which is to say how we focus exclusively on the human service dimensions; that is, people who apply for Medicaid often times also apply for ... and food stamps. So how might we facilitate the sharing of this information in that use case? Then the third scenario, the sort of über scenario: How might we achieve support for all of the above?

This is the picture. Pictures are helpful. The idea here was that we would begin asking the questions at the data element level and on the messaging standard level. What is it that we do to collect information from the applicant? How do we check that that applicant has either been already identified as eligible for something or could be? The could be part will come after we do the verification piece to make sure that the information they provided is accurate. Once that sort of ecosystem is completed it's sort of sharing of knowledge back and forth. Then the question is is there an ability for the data to be used for determining eligibility? Again, multiple use cases, either the framework itself will help enable the answer with the decision rules or could send the information on to another entity that will actually run the decision rules. Either way, at some point that information should be sent off to multiple programs or could, depending on patient consent or applicant consent and also, once the systems are complete, how that information flows back, both to the applicant, as well as to the, in this case, health insurance plans or other agencies that actually on-board them into the programs to which they're entitled.

I'm flipping through fast. I will quiet at this point and engage in conversation.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We thank you for a very exciting vision for the future. I think ... we've got that vision. There's been a lot of discussion today about the sort of governance relationship at a sort of oversight and policy level to the operations management and day-to-day tactical activities that you alluded to. One of the ... at the point of consultant posed policy specifications.

I think behind that was a thread that it's useful to have certain criteria to allow that conversation or the dialogue to proceed swiftly and with the characteristics that you described that are very practical as well, perfection not being the enemy of the good. I thought it was very resonate with the discussion on the difference between consensus and unanimity to ending up that in timely fashion and really, as we're obligated, to achieving the end result. So with that in mind, some of those questions may have ... the predicate of that history.

Let's work around the table. Chris Chute, we'll start with you. Thank you, Aneesh, terrific presentation.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Thank you very much. I agree. That was actually a very excellent presentation and I think the framework you're outlining is quite rational and hopefully will have the effect we all desire.

My question is rhetorical because I know the answer. We all know the answer. But I feel compelled to bring it up and when you're dealing with the linkage of such information and core information and it's the identifier problem in that it seems highly inefficient to engage in this kind of process. In fact, dealing with highly personal, confidential information with which you intend to treat with great respect and privacy. I understand that and security. Nevertheless, you have everything but the core. I appreciate that you're not permitted actually to answer the question more or less under some federal guideline, but I think at least from a public input perspective I feel compelled to raise the obvious point, which is this would all be infinitely more effective and efficient were there some designated identifiers permitted to be used within this context.

Aneesh Chopra – White House – CTO
What I love about this stuff is I sit in all of the committee meetings, as Walter described, the National Strategy for On-Line Transactions. Howard Schmidt and I meet literally every week on these issues. First of all, you are more than welcome and your voice is encouraged. Please describe how and in what manner such conversations should be had. We operate within a constraint where that is not current policy, so your feedback; don't feel like you have to, ~~-~~Hey, I can't say this. No. Say whatever you want to say. I have to work within the constraints of the environment we're in, but as I always do when this conversation comes up, I go right back to Halamka and his Health Pearl blog post, which still remains to me as one of the coolest ways to threaten this needle. As an interesting way to think about the question, let's all read Halamka's post and figure out if there's a way to do this. These are not easy issues. You're kind to say it. Don't feel like you can't share how this would work if you were present such ideas. Feel free.

M
The voluntary opt-in identifier for which there could be multiple service providers that would give you a URL that is persistent as a place to hold your identity and your healthcare information because Bill Clinton's executive order prohibits the notion of us having a singular, national healthcare ....

M
But the Halamka ... has potential.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We'll keep going around on this. Dave McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I'm just curious. The timing of Chris' question with the announcement last week about the initiative to create standards for identity, the federal initiative, can those be coupled together? Is there a possibility of –

Aneesh Chopra – White House – CTO
Yes. First of all, let me be careful in saying the report Walter referenced is the draft for public input.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Right.

Aneesh Chopra – White House – CTO
I want to be very careful. This is meant to gather input and all of these comments, please engage. That is a very important conversation to be had Walter made reference to. Was that link shared, by the way, Judy? Walter sent it around.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I sent it around. I sent it to the Security & Privacy Technical Committee of ours.

Aneesh Chopra – White House – CTO
I see. Maybe we can just send that around to everybody? Plenty of time for input I might say, David. So it would be encouraged. The lens with which that document was written starts with the premise of the government eating its own dog food. So how do we engage on these issues as we communicate and engage on activities on-line? Then how does that have an opportunity for thoughtful engagement with the private sector? So your input I think and, Chris, yours too, feel free to suggest how the bridge might work and how these things might evolve.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I will also note that just scanning a few blogs of a particular, political orientation in response to the initiatives, you understand why this policy exists, because of the fierce reaction ... reaction.

Aneesh Chopra – White House – CTO
Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Marc Overhage.

Marc Overhage – Regenstrief – Director
I hope to learn to hold my breath as long as you do, Aneesh, when you're presenting. It's an aspiration. The one thing that strikes me about this particular area, to some extent because of the mandate of your group you can side-step some of the many challenges of misalignment of what kind of data problems with eligibility test that have to be applied retrospectively, not prospectively and things like that. So I'm assuming all of that stuff is off the table, so that takes care of one page of notes.

Aneesh Chopra – White House – CTO
Well, look. Not this Committee, but I would strongly encourage; and I've got to make sure we make sure there's a linkage; there is a policy effort led by the Office of Consumer Information. I always get the OCIO, OIIO, IOOI – it is Jay Angoff's group and they're looking at what the framework might be as we evolve to 2014 and so all of that stuff is conversation that you should make sure that we have methods for engagement. Not that this is going to solve all of these things, but it's a great place to have the debate about how and why and so forth.

Marc Overhage – Regenstrief – Director
Absolutely. But even taking those things off the table, when you're looking at the standards gaps this is one of the places I'm guessing there is going to be a huge gap in vocabulary or terminology—

Aneesh Chopra – White House – CTO
Oh, yes.

Marc Overhage – Regenstrief – Director
You had on one of your slides MAGI, for example, which I had to learn about.

Aneesh Chopra – White House – CTO
Modified, adjusted gross income.

Marc Overhage – Regenstrief – Director

Absolutely. So you have issues of non-filers and so you've got to deal with missing or known to be unavailable data, things like that, which are, at least as we were poking around recently, looking for these kinds of standards we found very little presence.

Aneesh Chopra – White House – CTO
Oh, yes.

Marc Overhage – Regenstrief – Director
I think that the big gap here is going to be probably in your terminology or vocabulary space and importantly, the definitions that go around them, which is where you sort of get bridged back into the Policy Group because you can't have the terminologies without the definitions that go with them. So it gets to be a little bit of a—

Aneesh Chopra – White House – CTO
Well, the metadata is essentially the core question about it. So if I were to submit this data element, contains income, you'd want to know, okay, this is validated by the IRS with these conditions and it describes this aspect of it, so you have some clarity. So you're not that far off in the sense that we're not here to render judgment. Just accept last year's income—

(Overlapping voices.)

Aneesh Chopra – White House – CTO
But if there's a way to communicate what it is, has it been verified and so forth, that's very much in line.

Marc Overhage – Regenstrief – Director
I think that's all going to be new ground to be plowed. That's part of what the gap will be. The second observation: I was very glad to see you include call centers and things of that nature in the small P portal list. Some state that shall remain nameless went down this road not too long ago trying to put it all in line. Absolute disaster.

Aneesh Chopra – White House – CTO
I want to get that input. If you don't want to name then now that's fine, but I want to make sure we get that case study.

Marc Overhage – Regenstrief – Director
That's easy. The first pass at it college educated people couldn't complete. The second, tremendous problems. Eventually the entire investment was scrapped and went back to face-to-face—

Aneesh Chopra – White House – CTO
Oh, I know that state.

Marc Overhage – Regenstrief – Director
Not because of the technology and ability. You do.

Aneesh Chopra – White House – CTO
You have familiarity with that state.

Marc Overhage – Regenstrief – Director
I do indeed.

Aneesh Chopra – White House – CTO
And that was a high profile failure.

Marc Overhage – Regenstrief – Director
Yes. But I'm really glad that the people portal—

(Overlapping voices.)

Marc Overhage – Regenstrief – Director
That's a good point. Fair enough. That the people portal part of the telephone portal ... is incredibly critical I think to support, again, getting back almost to the definitions and things like that; that these aren't simple, intuitively obvious things for people to complete and so that usability aspect, as you're thinking about the standards, obviously, that may be again a little bit out of scope—

Aneesh Chopra – White House – CTO
No. No. No. No.

Marc Overhage – Regenstrief – Director
But whatever standards we encounter for—

Aneesh Chopra – White House – CTO
In fact, that's very much in the ... but look, what is liberating about the group we've collected is that we're hearing unique perspectives, so one perspective suggested; I'll paraphrase, because I'm probably going to get the quotes all wrong; but what if forget the government hosting any of these things. What if organizations could essentially bring all of this stuff together and so long as there were APIs that would allow us to exchange with the various parties we could do the verification, we could get all of the materials and keep it up to date with a change in status and all of the rest and then just serve up the information to the places that need it. So the notion of a ~~"p~~ortal capital P" under some of the conversation that's been had, it's sort of as long as the data is understood and the transmission and the methods, then there is a way to actually enable this to happen without ....

One of the interesting questions was simply so long as the agency has a machine readable and understandable rules construct, so the policy is you set the rule, but be clear about what those rules are so we can help to create calculators or automatic systems or whatever I will suggest to you, you will see flavors of this in the coming months.

Number one: I assume we've all been briefed on healthcare.gov. I forget. Did we? Come on, people. This is the most exciting thing that's going to happen since sliced bread. No. Tomorrow. Is today the 30th? Is tomorrow the 1st?

W
Yes.

Aneesh Chopra – White House – CTO
Tomorrow we birth this beautiful, elegant Web portal, lower case P, because we're committed to making this information downloadable and reusable so that anyone who wants to identify, you answer seven questions or whatever the final number was. I forget. You identify whether you, out of the hundreds of options available where your zip code is, here are the six things that you might want to consider. Oh, by the way, one of those six is private plan. Click private plan and you'll get the Expedia-like list with a statement that says, "~~W~~We will have pricing data in October." That's what I'm talking about.

It is exciting. You're going to see a whole methodology for how that information will be flowing through the ecosystem. That is, I think, a suggestion that thou shalt not feel so constrained that we're going down the path of another one, big, enterprise, complicated, system implementation effort. In fact, our data standard elements and concepts ... anyway. That's exactly right. You've got locals. You've got states. You've got the feds. You've got who knows what.

So in this environment I think if anything it's liberating, Marc, to think a little bit about if you had your dream how might you envision how we can engage that information and use it in a manner that is useful. This forum welcomes that input as long as we get to that line of communicate the rules electronically, but don't make this committee dictate what those rules shall be. You shall accept MAGI income definitions whether you like it or not. That's not in the scope of our group. I'm lecturing. Forgive me. You guys keep going.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, thank you. That is an exciting moment ... look forward to that. I'm glad we respected the anonymity of whatever state we just discussed. Nancy Orvis.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
That's great news that you're doing Healthcare.gov. Are you going to be linking that to the Benefits.gov site where you ask 50 questions and you can decide what are your eligible benefits? You need a hyperlink there.

Aneesh Chopra – White House – CTO
Yes. There are federal portals that have been around for years. One of them is the FedBenefits.gov. That has some very basic rules around federal programs. This is the health portal as called for by the Affordable Care Act, where our good friends in the insurance industry have been very active in populating. Anne, how much fun that was for you to help—

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
Not as much fun as October.

Aneesh Chopra – White House – CTO
I understand. It's all good.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I understand. It sounds good, but there are a couple of questions that says given this you are eligible for certain kinds of healthcare programs, so I would say you would have a big, new link to then say open up to Healthcare.gov.

Aneesh Chopra – White House – CTO
You got it.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Good luck.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Who has questions on this area? We have probably two other topics this afternoon. One of the important things about ... is that the public commentary. I want to make sure that in particular we continue the public conversation. Walter Suarez and Cris Ross, we'll close with your last two comments.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Thank you. This is amazing. It's an exciting time to be in where we are. All of these things coming out and together and hopefully putting all of this together in the right way I think is going to be wonderful. One thing I noticed about this and I tend to think too much maybe on transaction based mindset and so one thing I noticed about all of this is there are six or seven different transactions actually taking place in this.

Aneesh Chopra – White House – CTO
Yes. Correct.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Is the group looking at each of these transactions? What are the standards that exist to comply with or to execute those transactions? What are the data? Is that what—?

Aneesh Chopra – White House – CTO
Yes. No. No. The goal is to inventory those that exist today that are in use. They can be encouraged to be basically adopted. The other is whatever the gaps are. So, no, the transactions, a lot of the HIPAA transaction sets are actually at the core.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes. Exactly. But some of them, I would think there would be some gaps, like opinions or eligibility—

Aneesh Chopra – White House – CTO
Lots.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Verification information from IRS—

Aneesh Chopra – White House – CTO
Yes.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Some of these are ATM-like transactions—

Aneesh Chopra – White House – CTO
Yes.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
That might not be yet defined. So the next question is really with respect to those standard transactions or those areas where there's a gap of a standard transaction is the intent to go to a standard setting organization instead of—

Aneesh Chopra – White House – CTO
Correct. The question is what's the policy recommendation for how one would close the gaps. That's one of the recommendations that I'm imagining the committee— We've already seen the healthy debate you all had about NHIN Direct as an example of an effort to engage in a consensus effort to achieve an objective. So, lots of options and your input will always be welcome.

I'll be quiet after that. Maybe, Cris?

Cris Ross – LabHub – CIO
It follows pretty closely on Walter's comments, which is I think the Committee, which is terrific, did a great job of focusing on the eligibility issues really well. The real challenge beyond that is then enrollment and de-enrollment and re-enrollment and so on, which is substantially more complicated than eligibility verification, right? You can find out what you're eligible for and what is the data that will help me document my eligibility. Okay. Now when I'm done with that, now I need to enroll in something, especially with some of the new programs that have a consumer choice aspect too. It's a big deal.

The reason I wanted to raise it is not to belabor the point, but I think one of the things we were trying to aspire to is to figure out are there ways that we could combine the administrative and clinical data domains in some usable, sensible kind of fashion. So maybe it's just getting back up on my NHIN Direct hobbyhorse again too, but all of this stuff is going to require sophisticated, multi-part, synchronous over a long period of time, set of transactions. It's not just a one query. It's not just to send a data point once. It's going to be in communication between a group of agencies and an enrollee over a fairly long period of time with a fairly significant amount of orchestration. So if we're thinking about bringing clinical and administrative domains together I think this will raise some challenges that will cause us to, I think, beef up our thoughts about NHIN Direct.

W
I would just like to add, just remember, this population, a large part of it, will now become newly Medicaid eligible and it will be income based and they will be in and out of eligibility, so the length of time for the enrollment and the disenrollment is going to have to get shorter and shorter in order to keep these people covered by some form of healthcare.

Aneesh Chopra – White House – CTO
Can I have a homework assignment and I'll be quiet after this? To my brothers and sisters from the hospital community and I'll look at you, Cris. I'm looking at Judy. I'll look at you, Walter. If you could ask your billing people and your finance people today when someone who's uninsured comes in and they go through heaven and earth to try to get them enrolled in a program, to bring up the insurance, help us identify what creative ways they do that electronically. Where do they find frustrations? I think this is a great opportunity in our conversation to invite others within the healthcare ecosystem. Not a lot of folks around this table are that familiar with enrolling people in food stamps, per se, but your friends and sisters on the finance side have some exposure here. If you would be so kind as to bring that input back I would greatly, greatly appreciate it.

Okay. Let's rock and roll.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, thank you very much, Aneesh. We greatly appreciate it. I know there are some further thoughts, but we'll respect we're at the hour and your time. I appreciate all of the hard work of the entire group. It sounds like we have a homework assignment to bring information back to Aneesh on enrollment.

Let's segue now to the Clinical Quality update. Floyd Eisenberg and Janet Corrigan are here to give us that update. As they're moving to the podium I'd just note in terms of the last sort of conversation that Cris Ross offered, that it really is a segue to some of the concepts that are embraced and the information discussion in the Clinical Operations presentation later this afternoon. Nice segue to that concept. Before that, right now, we'll go to Clinical Quality. Thank you, Janet and Floyd.

Janet Corrigan – National Quality Forum – President & CEO

Thank you, John. Great. All right. Well, we have several things that have been under way since the last time we had a chance to update this group and wanted to really cover three things today. First, Floyd is going to give you a little bit of an update on where we're at with the re-tooling of the 2011 meaningful use measures. A lot of work has been going on the last six weeks or so. Floyd hasn't had a lot of sleep lately, but we have managed to get the first sizable batch out, so I think we're moving along well.

Second, we want to provide you with the results of the environmental scan that was conducted on the leading health systems or basically the health systems that are represented around the table that we asked to help identify what they thought might be good measures for meaningful use in 2013 and 2015. We have the results in from that.

And then, third, we're going to share with you a little bit of an overview on a fast track project that NQF was asked to do by ONC. It's a project that will pull together some information that hopefully will be helpful to inform the deliberations and decisions of both the Policy Committee and the Standards Committee in the fall and sort of looking ahead and anticipating certain types of information that are going to be needed at that point.

Floyd, why don't you tell us a little bit about where we're at with the re-tooling of the 100-and-some measures?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Sure. Thank you. I also want to give credit to the staff at NQF, at AMA and NCQA that have put in a tremendous amount of hours. I wasn't the only one without sleep in order to get these things done right.

So we have now delivered 44 ambulatory measures with a human readable format and spreadsheet containing all of the code lists. We have learned a lot in this process. We have used the quality data set, the data types to identify all elements, applied logic in human readable format, provided list of codes of value sets for each element. In doing so there are a number of learnings to help make this more efficient for the future. This was a very valuable project. When the dust settles a bit we'll be able to come up with a list of what some of those common issues are to help move the whole process forward to electronically defining measures from here on out, not just re-tooling, but tooling. We also have an authoring tool shortly in development to make this more automated, but a lot of these learnings will certainly lead to improvements in that area.

The next thing I can talk about is—

Janet Corrigan – National Quality Forum – President & CEO
Before you jump out of this, hang on one second, Floyd. The other thing that's come out of this initial batch of 44 measures and the remaining 60 or so measures will be delivered the next couple of months. This was the first batch that was prioritized highest for us by ONC and CMS together, but one of the things that's also come out of this is that it generates a lot of value sets.

So this issue that we touched on before and that Jamie's workgroup did quite a bit of work on a few months ago that had to do with the value sets is going to be a really important one going forward because we just see the potential for the proliferation of value sets and to undermine their efforts to standardize how we are measuring various aspects of performance, unless we get a handle on these value sets and figure out how we're going to make sure that they're only created anew if there isn't one that can satisfy the particular purpose that's under way. That will be an important thing to return to I hope and that we can find some sort of solution to who is going to manage the repository of value sets, because this is just a small area of performance measurement. Of course, we've got clinical research and comparative

effectiveness and public health and population health and other groups that are all going to be doing the same thing for different purposes. We all need to be using and working from the same value set repository. Go ahead.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Exactly. I think Jamie may have some comments on that from the Clinical Vocabulary Task Force that met yesterday. Will that be in your report?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No. Actually, we're just in the process of planning hearings on that topic, so those hearings, we'll be able to plan those approximately over the next month. We're working on a schedule for those hearings on the vocabulary repository infrastructure, so I was not planning to talk about that today because we're not ready with the complete plan for those hearings yet.

Janet Corrigan – National Quality Forum – President & CEO
Great. Thank you.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Okay. So moving to the next slide and that's the results of the environmental scan. Twelve leading healthcare systems were queried and we had nine responses. The respondents are listed here. I won't go into detail on individuals, but in looking through the list there were a number on diabetes. The first slide, actually, all are highlighted in yellow to indicate that there is either the same measure as defined in what was suggested or something very similar to it in what was already delivered in the first 44 measures for ambulatory care in the just completed retooling project. Some are similar.

For instance, hemoglobin A1c, there is a measure looking at A1c less than 8. The decision on whether it's 8 or 7 is a more complicated issue that does need to be discussed and which is actually appropriate. What actually will help as this is looked at in the future, this and others, like blood pressure, is to be able to identify the data electronically allows you, for any individual patient, to think about a delta from point A in time to point B and has that patient actually improved. Where there is evidence in areas like hemoglobin A1c improvement or blood pressure improvement or weight improvement it may be an area to take these concepts that are in current measures forward to the next level.

If we look at diabetes as one, one issue in diabetes, we do have tobacco use measures, but not specific to diabetes, so certainly one suggestion could be from this kind of scan to stratify it by condition if necessary. Preventive services: All of these screenings are in existing measures; weight management; blood pressure. I mentioned the issues of knowing that it's below a certain value or has it changed. A change would be a future enhancement on those kinds of measures.

On the next slide, Healthcare Associated Infections, there are three that were listed. In fact, those three specifically are on the list that is being evaluated for the next round of the retooling that we're doing now. Some of the others are newer and are not necessarily in the current list. There is one that indicates the appropriate use of high risk medications.

There is one for drugs to be avoided in the elderly that's in the next round, but many of these will need some further work, so safety events. Medication management and compliance. Patient experience. The recommendation was around survey scores, but there may be more detail exploration to identify patient experience beyond the survey. Staffing and turnover rates in skilled nursing, chronic care and use of restraints in care transition. Re-hospitalization and stratification of disposition. There are also some

home care measures recommended, including management of medications, grooming, meal preparation. So that's the list that we did receive.

Janet Corrigan – National Quality Forum – President & CEO

Now I want to spend just a couple of minutes on this Fast Track Project because it's aimed at producing some information that hopefully will inform some of the decisions of the Policy Committee and the Standards Committee in the fall. Recognizing that we have to move very quickly to be prepared for the selection of measures for 2013, especially if additional work is required to generate those measures and get them tested and endorsed, we've got several things sort of going on in parallel that if we had all of the time in the world we'd probably be doing them consecutively, but we don't, so we're kind of operating on parallel tracks.

One of the things that we were asked to do at NQF; and I'm taking off my Clinical Quality Workgroup hat; this relates to the work, but it is a project that we were asked to do is to identify the types of measures that might be appropriate for 2013 by pulling together several streams of available information. One of those streams of information is the one that you just heard about, which is the environmental scan.

A second one is the comments that were received on the meaningful use '11 measures that also identify. Many of them said, "We wish you had picked this kind of a measure," or, "Why don't you select measures of this type going forward?" So we're looking at those comments.

A third stream of information is a list of measures that the Beacon communities have started to assemble where they think that it focuses on particular conditions, as well as certain types of measures, so for example, diabetes is one that virtually all of the Beacon communities have identified as an area they really want to try to push on, but there is now a growing list of measures that the Beacon communities are focusing on.

A fourth steam of information is a small thought group that Elliot Fisher and I co-chair that Jim is a part of and some others that are trying to think through 2015 where the puck is going; that's why it's called Gretzky Who; what measures would be best for 2015 and then back into some 2013 measures.

There is also a sizable effort under way that NQF has under a federal contract to develop a measure, an agenda for measuring development. That is looking at a wide variety of issues that impact the types of measures that we might want to focus on in the future.

So taking those streams of information, coming up with a list of measure concepts that would be good to focus on for 2013 and we're using a two-dimensional framework. It's the National Priorities and the key areas that the Policy Committee has already identified in its framework, but then also the second dimension is leading conditions. What we've done so far is to assemble this fairly sizable list of measure concepts and then identified a set of tracer conditions, narrowing down from about 20 to about 6 to 7 conditions that we think probably would be really good ones to focus a lot of effort on.

Then the second step in the process is to identify the state of readiness of measures for each of those measure concepts. So for each of the measure concepts we're looking at whether or not there is currently a measure available that matches right up to that concept. It's fully tested and ready to go. That's the best situation. Second, if we don't have a measure currently available is there a similar measure that's then developed that could potentially be adapted for use in 2013.

Then the third scenario is if neither one of those is true then we're in a situation where measures would have to be developed anew. This particular effort will be producing a report in about 30 days from now,

not very far off, that will identify and categorize each one of those measure concepts and the state of measure readiness. So when the Policy Committee meets in September it's our understanding that they're going to turn their attention to providing guidance to us at the Standards Committee as to what they would like to see in terms of measures for 2013, so this will help to inform their decisions because there will be a lot of ideas on the table for what would be good to measure, what pushes the envelope, but then there will also have been a pretty thorough analysis of what measures are currently available to meet those needs so their decisions can be informed by the feasibility analysis; that's what it really is; as to the potential to actually generate such a measure by 2013.

In addition to that it will probably be quite helpful, we hope, to HHS, because they'll at least have an initial list of areas where it might be good to pretty quickly provide some support for rapid measure development. They may choose to start to get those contracts out in the field sooner rather than later because it takes at least a year to put together a good measure and test it and actually move it forward for consideration. It will help our Standards Committee discussions too because once the Policy Committee comes forward with its recommendations as to the direction they want us to go, presumably that will overlap, at least in part, with this initial piece of work, so we'll have done much of the homework on the availability of measures going forward.

I think one of the things too though, another issue that I did want to raise, a couple of them, and Floyd has alluded to one of them: As we look to 2013 or 2015, ideally, one wants to begin to look across the full longitudinal care episode, so in 2011 all of our measures are siloed. We didn't cross settings. That's understandable. But in 2013 each one of these various groups that kind of weighed in on this or provided information wants to start looking longitudinally. You'll want to be able to not only look at readmissions to your own institution, but to all in the community. You want to be able to look at patient outcomes. You want to be able to look at the total cost of the care episode over 6 months or 12 months. When you pick a particular condition many of these are very amenable to trying to do that.

It does raise an issue though, especially as we look to outcomes and health status measures as to what assumptions we all should be using about the types of measures that would likely be candidates for 2013 and how that information would be gathered. So, for example, if SF-12 or SF-36, the common health status instruments that are in use in many areas right now, I know Veteran's Health Affairs actually is using a version of SF-12 ... 12, I think John has been for quite a few years. Quite a few of the measures would like to be able to make that association between process and outcomes and would really like to be able to also look, as Floyd said, at the delta, the change in health status or health behaviors or outcomes from one period to another and then try to attribute that, at least in part, to the healthcare interventions.

That really does point then to having to think about what data captured in personal health records and the extent to which this effort is really going to promulgating measures that would likely not be captured when the patient is having an actual physical encounter in a healthcare system. So, some guidance in that particular area would be quite helpful because there is very real interest on the part of all of the groups that we've dealt with in moving more towards outcomes, health functioning, health data and health behavioral measures.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you for a terrific and robust presentation. I understand why all of the workgroup members have not been sleeping. This is a huge amount of work getting ready for 2011 and thinking about 2013, the environmental scan, the report that's forthcoming and then really thinking about the segue from point measures to continuity measures to help to improve care and value ... that may be populated with data, as you've indicated, from sources that are outside of the current formal in-patient or patient care settings.

Indeed, that functional status is really a pretty robust indicator of well being and outcomes and therapy, so a lot to think about with that.

I see some cards are up. We'll start with Karen Trudel.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
Janet, in the comments that we got on the meaningful use regulation we got a lot of input about the lack of measures that were appropriate for specialty practices. Where do you think we'll be with respect to those kinds of measures in 2013?

Janet Corrigan – National Quality Forum – President & CEO
That's a real challenge to try to get them that are applicable to the many, many different specialty areas that are out there. One of the criteria that the little Gretzky groups that I talked about has adopted to try to prioritize or think about what areas might be most important is whether or not the measure is one, how broadly applicable it is and so they're really giving a preference to those measures that apply to multiple specialties or all specialties. Some of those are sort of the cross cutting measures, whether it's the care coordination, whether it's generic measures of health function often times can cross many, many different areas. Sometimes you get into one that you need very specifically depending upon the application.

So I think it's a real challenge to come up with measures that can apply to as many as possible because another one of the criterion that the group is talking about is parsimony. We don't want to overwhelm the field with so many different measures because there is clearly a cost here and people can only focus on so much, so to the extent that you can have a more parsimonious and focused set, that would seem to be desirable as well.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you. Let's see, let's go around the table. Judy Murphy, I think you were next.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Sure. I would like to put the plug in for the 24/7 caregiver nursing and when we think about categorizing the quality measures that we really take into account nurse sensitive measures. Now, I know on the environmental scan quite a number of them came out falls, use of high risk medications, catheters, pressure ulcers, but I think it's a giant category of stuff that we really haven't dealt with yet and I'd like to see that as maybe one of the types of measures.

Janet Corrigan – National Quality Forum – President & CEO
That's great. It's a great point and I think many of those measures really do resonate so well with the long-term care community as well, so they can cover the full spectrum of services. That's another criteria that's being considered is whether or not the measures really do cover multiple settings as well in the full longitude. That's a good point, Judy.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Without opening up the bill I can't remember the number of different CMS programs times care settings that are identified in the DBACA as pilots or some other stage that has a measure of quality associated along with it. Is there a roadmap somewhere that lays out all of those against your work or identifies where other organizations are doing work? How is that being coordinated?

Janet Corrigan – National Quality Forum – President & CEO
Yes. It is a very, very dense piece of legislation and there is one roadmap that's under development and almost complete, actually. We are working with RAND to catalog all of the payment programs and to then

lay out their implications for the types of measures that we need to have ready and available to move forward for use in those payment programs. So that covers the demonstrations and pilot projects, as well as the changes in the mainstream programs, Part A, Part B programs, for example, the penalties if your readmission rates are too high or your healthcare acquired conditions that affect virtually all hospitals or all types of providers, but then also, it really is all of those creative programs that are out there.

So one can catalog the programs, but what there really isn't a roadmap for yet is what types of measures are needed. That requires some real analysis to think through what would be useful. What's appropriate given the unit that's being paid in terms of attribution of the measures and if, for example, a bundled payment program for a chronic condition you probably want a set of measures that are both, process and outcome measures in patient engagement and decision making. So there are efforts under way to at least look at it through the payment lens in particular.

There are also a couple of efforts that are trying to look at how the public reporting Web sites will likely evolve. Of course, we have the physician Web site that's going to be coming up quite soon and expanding probably quite rapidly. We're all trying to figure out how at some point it jumped to patient centered Web sites that are not in the silos or that complement the ones that we currently have that are siloed, because we really want to be looking at it more through the patient's lens.

I think this is one of the challenges that ONC and we all have on the meaningful use side is that you really have to be thinking about the selection of measures that are not only the best and most appropriate for meaningful use, but that also kind of fit in with that broader set of needs because I think from the provider's point of view they don't sort of separate out those meaningful use measures here, the payment measures or the public reporting measures here. It's just a lot of measures. So it all needs to kind of add up to a coherent framework. I think that there has been a lot of really good effort. I have to applaud both ONC and CMS for working so closely on this and trying to make sure that these pieces do come together in a coherent way. That's very clear from the efforts so far. I think that's real important.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I just didn't quite hear. There is a roadmap being developed for payment based programs in the DBACA. Is that right? That will become public at some point in the future? Is that it?

Janet Corrigan – National Quality Forum – President & CEO
Yes. It will be public probably in about six or eight weeks from now. The work, as I said, has been done by RAND and they submitted the draft report that's being reviewed and will eventually go out for public comment on the NQF Web site.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific. Well, in addition to a terrific report that will be a well anticipated contribution. All of us who are interested in measures will look at that ... principle as well. I think everyone is committed to improving the care and the degree to which the measures are not similar, but in fact, identical and overlap ... framework that becomes all the more powerful. Thank you very, very much, Floyd Eisenberg and Janet Corrigan, for your terrific work and that of the workgroup.

Our last formal presentation of the day is the Clinical Operations Workgroup. Jamie Ferguson is going to be presenting that update. We've had some discussion about the ability to use templates and extend and reuse templates in other existing documents. That really extends, I think, pretty much the discussion

earlier about potential overlaps between administrative and clinical data. It brings it back to a very practical set of aspirations for the use of health data for better care. With that, Jamie.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Unfortunately, for those of you who have received materials here in the room, the first two slides of our deck did not print. However, they were in the materials that were distributed both by e-mails and download, so the full document is out there on the Committee Web site and will be displayed here, but it's not in your printed package.

So the important slide that I think is missing from the printed package is this one, which is our problem statement. I think when we think about CCR and CCD they're very useful for exchanging summaries for ambulatory care, particularly in transfers of care. But we've received requests for some additional work from John Halamka to provide input on document standards, in particular for discharge summaries and for potentially other purposes.

So we took a look at the existing standards, CCR and CCD. We found that they have exactly the same template content, but there were some things that were not there that were needed for the discharge summaries and so there are some examples of that missing content here listed on the slide, the discharge diet. The chief complaint is one that I think, John, you ran into in a practical example as being missing. Anything else you want to say about the problem statement?

John Halamka – Harvard Medical School – Chief Information Officer
There is a challenge. Meaningful use requires demonstration of provider-to-provider exchange and the requests we get in our community are when a patient is discharged from the emergency department and send a summary of emergency care back to the primary care doctor. When a patient is discharged from the hospital they send a discharge summary or send a surgical summary. These are just very common summaries.

So here's what we ran into: The CCD or the CCR are fine if you have problems and meds and allergies and labs, but as you said, Jamie, these are really more a summary of the patient's lifetime record than the episode of care that was delivered for which you're now informing the primary caregiver.

So our coders then went to say, "Where do I put the chief complaint?" The answer was we were inventing standards for our particular purpose, which seemed just silly. The last thing we want is a CCD that's been modified by every hospital for what is a standard document, the discharge summary. So I asked Jamie and the group, "What do we do?"

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So I just wanted to take a minute to review. So where we're starting from is we had in the IFR the CCR and the CCD and so the relationship is that the CCR developed a number of content templates that were then put into the clinical document architecture to form the CCD. So one way to think about it is the simple formula of CCR plus CDA equals CCD. But the content templates are identical between the two and so then when we look at the need for some of these additional data that are not in those particular summary documents the question came up how would we extend the existing summaries without redoing things and providing reuse for the existing content templates that were already in there.

We found that, in fact, there is, I think, a pretty well recognized group of content templates in the clinical document architecture that can extend that work that was done in the CCR and the CCD, really, by extending the CCD. So in fact, there is a transformation because the content templates are the same.

There's a transformation from the CCR into the CCD and then the extension can be accomplished by adding additional CDA templates.

Now, one of the particular parts of the problem that John had brought to our attention was that of document identification, so documents have identifiers, so there's a particular identifier that says this is a CCD document and so the question was if there are going to be different flavors of adding templates to that CCD then how do you identify those additional new documents. I'll come back to that in a minute, but for this purpose I just wanted to say that there has to be an identifier for the CCD as a summary document, but there also has to be an identifier for the example here is an emergency department discharge document as to if it's going to be a standard document it has to have an ID that identifies that particular document.

Are there any questions on the general framework here? Yes?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David. So the identifier would be a template identifier when you ...?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, I mean ultimately there has to be an identifier for the complete document. Now, there are a number of different ways of accomplishing that. Let me get back to that question in just a minute, okay?

M
... this question, which is how many discharge summaries did we send? How many ED summaries did we send? How many ambulatory summaries did we send? We figured out there's actually no way to answer that question unless there is some metadata that describes the thing you are sending.

M
... instance identifier. It says this is a discharge summary—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Correct.

M
To me it's a template, but maybe that's the wrong language.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay. I saw Carol and then Wes.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. So I have a question. This has been nagging at me for a really long time. I'm not sure what the answer is or if there's any way to think about it, but one of the disadvantages of a document based approach to these things is that there are an infinite number of documents in healthcare and an infinite number of needs to transfer information. I'm sitting here thinking, "Well, I don't know. A discharge summary and an ambulatory summary, they both need chief complaints." I mean there's just an endless array of documents. I don't think a lot of the documents have a lot of consensus and I'm just worried that a document based approach is almost like taking the paper world and trying to make it digital when the digital world affords us much more flexibility.

I'm thinking of public health as well. Public health reporting. Are there going to be separate documents for that? Because there are different fields there that are required. I just need to ask the question of

whether there's a more efficient modular approach to the elements of the EHR that need to be harvested, when they need to be harvested in a standard way as opposed to there may be good reasons for doing discharge as a document, but as opposed to having this endless array of documents and then a document index and identifiers and all of this other stuff when a lot of the information in these things will be overlapping, not identical, but overlapping.

(Overlapping voices.)

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Let me just do a quick response to that and then I'll go to Wes because I think we're certainly very aware of that. It's probably a good idea to take a more fundamental re-look at this as new requirements come out from the future policy and future rule making process. Just to reiterate though, the particular problem that we had here was the extension of the existing adopted standards, not to have a completely different view of it, right?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Just the right chassis on which—

M
... definition here. A document in a sense is a structured set of specific data, not a document as –

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
No ... really a document. I mean it is really a constellation of elements in the CCR and CCD and each time you want to have new data elements you basically create a new – that's why we have to do a discharge summary document.

M
Well, and that's what we're talking about here. To answer your question, imagine that, let's say for the ED, for the discharge summary from an inpatient stay for an outpatient stay there are 100 things I want to communicate. I actually, even though my discharge summary may look different than your discharge summary, I don't want to have to invent the template called chief complaint. I just want to list some pieces off the shelf and send them as a collection of stuff.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, in fact, I may have erred by asking for comments on this particular slide because some of the questions may be answered in the next couple of slides. Let me slide through those and then we'll get back. I think Wes is next, okay? Sorry about that.

So, our overall plan is at the end of the day we'd like to make recommendations to whatever the right entity is, the standards of harmonization entity or another, whatever the right entity is in terms of the framework that we heard about from Doug today. But at the same time, we think that we can provide some guidance as to how that ought to be accomplished. So without being particular about what are the templates, what are the exact standards, what's the exact process, I think we are providing higher level guidance in terms of the general direction of standards that are needed and also, we did have participation from this on the workgroup and this idea of extending the existing adopted standards through additional identified templates is very consistent with their direction for testing.

Another thing here is that, as Carol was saying, we need to be able to enable more documents and yet still reuse the existing work that exists in these current templates. We also had some consideration about

recommending this direction for attachments. I think we'll want to have further discussion about that as new attachments may be required in the future.

Now, I did want to get back to the point of identification because I think, as Carol was pointing out, there is a potential ... explosion if you have an endless number of these templates. But we did have a brief discussion in the workgroup about a couple of potential ways of handling that so that you wouldn't have a complete enumerated list of all of the complete documents because there are ways of either concatenating template identifiers to form document identifiers or embedding them within the documents and so there are multiple methods that could deal with that identification problem without having an enumerated list that runs into the ... explosion problem.

Another area, and I think, Janet, this is really for you, is that we recognize that there is a need for closer coordination with the value set standards for particular measures. The example that we used in our discussion was the discharge summary requires certain templated or certain standardized data. If we're going to have a standardized discharge summary then there needs to be a set of standards for the content there and yet at the same time we have measures for hospital readmission that may use exactly the same data and so we recognize that there needs to be coordination across these different efforts. I think that should fit well into the framework that Doug talked to us about this morning.

So now, having said those things, you know we're very interested in getting Committee input. I think, Wes, you're up next.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thank you. So, this morning Carol asked a question about optionality and although I don't know if there are any words, the non-verbals expressed some distaste for optionality I thought.

W
....

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. But here we have an argument for optionality, okay? Right. Here we have an argument for optionality. Having been around this block a few times, I think I hear a thread of two things. One, there needs to be a way of continuing rather than ... existing standards work. And two, as we look at what we've done so far and we go forward, the notion of fixed document content may be a little rickety. So we get CCD as a profile on CDA. There are various profiles on CCD and effectively Stan and I were having a discussion at lunch time about either CDA or CCD has to become the version three message of the world.

I would suggest that the difficulty with optionality is that it creates a set of implicit business rules. The sender can't know whether the transmission is acceptable to the receiver until they're told it's not. The receiver, in theory, has to program for a wide variety of differences in the document if they do it any other way, so I would look for some mechanism that effectively states a minimum and a relatively free way of adding material to the minimum as opposed to – I think that may be where you're heading, but I just wanted to get that out.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No. That's exactly right. In fact, one of the things that was on, I think, the prior slide that I didn't go through in detail in the interest of time was that we did have a discussion. In fact, at this point we would recommend a direction towards having some relatively limited set of complete documents that are

specifically enumerated and identified and then have some mechanism for potentially expanding it on a more optional basis.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Adding more information to a specific, defined document?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
To a specific defined document on a templated basis. Right.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thank you.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Member of the Committee. I have a lot of thoughts about this work and where we're going and Jamie and I, we discussed during the meeting on that. For one example I could say right now that DoD could offer out a sample implementation guide of a military health system discharge summary that we gave to federal health architecture three years ago. We very much were committed to the fact that we would use XML based standards to commit this kind of information. My plan would be that if any organization wanted to get a discharge summary from the military healthcare system there was one implementation guide and one way to ask for it, just like one way to check eligibility, one way to check enrollment. It's extremely important for that.

Yet, I'm in a situation where we have been cataloging over 2,000 paper forms from Army, Navy, Air Force health records over the last 50 to 75 years, which still also have to be part of the record. I think you have to be realistic that you still will have to have this cataloging because health records people, insurance companies will still need to have, "I need to find something in this category about this patient," and it might have happened 20 years ago. We're going to be in this mixture of it's not the whole brave new world, but everything is starting from ground zero and there's nothing except electronic data. So I just wanted to put that out there as a very real issue.

As a sidebar, I think the fact that we, as federal agencies who give healthcare, have under personnel and records administration, we already have a commitment that we must keep those records under laws of personnel records for 75 years. Now, the rest of the American culture does not. We have not even talked about that policy on how long are people going to be – who is responsible for keeping a person's medical record for their lifetime, but I think that's one that has to be addressed in the next few years, because that to me, as a civilian, I don't have anybody keeping my record for 75 years. I have to figure out what I'm going to do myself. That plays into this issue of how we are going to talk about where are we going on templates and clinical documents because we are all going to be having a mixture of paper and electronic or scanned paper.

I believe also that I feel pretty strongly that the CCD, when it was created as a CCR template with an XML base, at that point in time it was not intended to be the basis for all future clinical documents. It was created for a particular need. A patient is going to be transferred for care from one doctor to another and trying to make that fit all needs is going to put us in a box canyon that we don't want to get out of, that we won't be able to get out of. We need to go back to the original idea that we had clinical domains of knowledge. You might be able to template or identify that and go back to build towards the future and not just adding on to that continuing care summary. It does not meet. I think there are very few cases in the United States where the majority – we're not transferring patients from one doctor to another for the most time. We're exchanging a lot of information while they stay in a medical home or they are under the care of another team, but we are not transferring. That CCD is a very constrained use case.

So I just want to make sure that as we work on this we will all continue to ask for more input on that, but we definitely need to keep the big picture out there. We need to be looking at the fact that these are longitudinal records that we're building and that there are multiple ways that we are going to have to search for them in the simplistic way and in a complex way. We're not going to get to the complex way all at once. We're going to need to still keep, I think, with some categories that are basically understood by all medical records people, by clerks, by doctors, everybody else. So those are my comments on this and I'm happy to let anybody look at that discharge summary implementation guide if they'd like to see that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, Nancy. Great points. Take my advice. Don't calculate your age in 75 years. David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes. A few things that security issues around NHIN Direct are controversial, get into the document versus messaging debate. It's obviously gone on for a long time. Wes is gone, so he can't chime in, but just a couple of thoughts.

One: Carol, I think the medicine is as much about trajectory as it is about current state and you need to be able to reconstruct the story, so you can't just send a current snapshot and say, —This is how the things are now." You have to say, —This is how they were at a point in time," and then give someone the ability to reconstruct them. At least that's how I think of it. So documents do a nice job of a snapshot in time and somebody can say, —Well, that was five years ago and look what we were doing then and it didn't work, so let's not try it again." I mean that's valuable information.

The value of a CDA or a CCR, whatever XML approach you choose, is that you get the benefit of structure, as well as the snapshot in time, so it's narrative, but it's not just narrative. You can extract out of it and trigger rules at the moment ... and things like that. But I think it would be a mistake to only have documents and not have data transactions that say, —Here is the current state of truth, which is really a message model, because you need to be able to reference previous knowledge and say, —This is no longer true," which a document can't do. You can't negate something with a CDA. I mean it just adds. There's no way to take stuff away. There's not a transaction ID in there, for example. So you need them both. You need messages and documents, but I think it would be a mistake to collapse them into one purpose.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Since a lot of the comments have been directed back at my original comment, my question really was about the chassis of the CDA being the longitudinal strategy –

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
And less about the purpose of the information sharing, whether it's a snapshot or a long-term view. I'm not arguing for optionality. I think the clinical domains need to be standardized.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes. Yes.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I'm questioning whether the chassis is right. That's really the question or whether it will serve us in the long-run.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, on the comment on ... explosion question I don't think it's an infinite explosion. If you look at the library of documents that are managed by a medical records department at a large hospital I'd say large number, but it's not an infinite number and it's ... tailing off. It grows with knowledge, with the addition of new kinds of medicine, but it doesn't grow infinitely. But the best way to describe, the best way to span a complex space is with orthogonal basis factors, which are reusable modules. So to the degree that we get the modules right then we can have a large number of variations in those modules and whether they get a new, unique number or just a dotted orthogonal vector, that's a technical debate that we should have. Anyway, enough said.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We're going to be respectful of bringing a public comment in before we lose that line, so let's plan on two things. Let's plan on starting our discussion next time with a continuation, because I think this is very rich. It's clear from the context of the discussion there is a specific role. I didn't mean we had to go to that right this second because I still want a very quick update on the certification process, the basic facts from Steve and Carol Bean, but I think this has elicited a very good thread of discussion about where the utility are, where one needs standardization and both, some concepts about trajectory of the ... and richness and other uses of information that have been very much supportive of your comment. So I think there is the box of what are the appropriate uses of this document and templates and then what are the other elements of information that need to be contributed to complete the picture and provide the utility.

Let's finish with this thread of discussion. We'll put it up as the first topic of our next discussion next time. That was Chris who had a card? Yes. Chris Chute, I think you were up first going around the table.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Well, I was just going to address the issue of CAD-3 components and the common ... issue that we had discussed. I guess we don't have time to go into it in depth now, so if we can take this up next time that would be good.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We can commit to that. Stan Huff and then Cris and then a quick update from Steve and Carol.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Again, we don't have time to go into it, but there are other mechanisms that we haven't talked about, which include LOINC and LOINC panels and the idea basically that it's just an extension from some of the things that Dave was saying. I could just ask give me the history of hemoglobin A1cs and the easiest way to do that is to send them an HL-7 message with all of the hemoglobin A1cs that are time stamped as OBX segments. That's much more efficient. It gives you all of the time stamped information so you can do whatever you want with that and so I guess there are other things that we haven't mentioned yet that, in fact, would be very nice mechanisms that could be brought into play to help solve some of these questions.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
If I could just respond to that very briefly, just to reiterate, the problem that we were trying to solve was cases where documents are needed for particular purposes and so that's true, I think, for the discharge summaries. It's true for some of the attachments, which is one of the other use cases that we discussed, but it's not for everything.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Right.

Cris Ross – LabHub – CIO
It has overlapped, but LOINC is making LOINC codes for all of those sections that are in the CDA documents and there are CDA document implementation guides and then there are panels in LOINC and the panels in LOINC are specifying the container and other LOINC codes that are contained in that container and so logically it's identically the same thing as doing an implementation guide, but you're doing it table driven rather than document driven, so your table driven, which gives you the opportunity to do things much quicker and they're directly computable. Anyway, I mean you're familiar with this. I'm not.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay. Well, thank you very much. Jamie, thank you very much for a terrific and provocative discussion. I think the meta message from this is that what is the use case you're trying to address, what are the complementary technologies to address other use cases. Great work. I think a terrific framework. It dovetails with the work on Clinical Quality and it's a topic we'll come back to next time as well.

We have with us from ONC Carol Bean and Steve Posnack. Let's just do the highlights of the Temporary Certification Program and we'll come back, as well, for any further discussion on this. I know today has been a very robust agenda. I appreciate, really, the important discussion, not only about the work of the group, but the process of the group related to issues of governance and the relationship to NHIN, etc. Carol and Steve, you're on.

Steve Posnack – ONC – Policy Analyst
... after all, your main course is there. So a very quick update. We also have to go. I know probably some of you from out of town need to catch flights and other transportation. We have an information session at 4:00 that we need to get back for, so just a brief history.

In the middle of March we published a notice of proposed rulemaking for both the temporary and permanent certification programs. We acknowledge that we would finalizing them separately in order to expedite the processes to get authorized testing and certification bodies out for the Temporary Certification Program in synch with the Meaningful Use Stage One Program. So we got that rolled out. It went on public inspection on June 19th. It published last Thursday. If you do the calculation on dates it was a pretty quick march through the rule making cycle with the final process from the comment period ending on April 9th to the publication date being about nine weeks, so it was a very trying task to get everything done, but we worked through it as fast as possible.

I need to thank, like I did at the Policy Committee, Mike Lipinski, who is also back at ONC, who helped contribute a lot of the drafting to the Temporary Certification Program final rules. So again, it's a big first step that will send into motion a lot of the processes related to meaningful use, essentially laying out the process that the National Coordinator will take to authorize testing and certification bodies under the Temporary Certification Program.

It also sets the parameters around the testing and certification of EHR technology, both complete EHRs and the EHR modules, as they were defined under the interim final rule. So we've got one half of the equation kind of set up to get up and running.

I will turn it briefly over to Carol.

Carol Bean – ONC – Director, Certification Division
I would like just to provide a little bit of information, highlighting what's coming next and the timing of important milestones over the next couple of months. We are in the final stages of preparing these applications, which are fairly complex, for distribution to those who would desire to achieve authorization to perform the testing and certification of EHR technology. The new acronym is ATCB, as Dave told you, it was Authorized Testing and Certification Bodies. It just rolls right off the tongue very easily. It will come easier as you get used to it. I have another one we'll save.

We have already received about 40 inquiries regarding these applications and at this point have about 15 formal requests for them, so we are confident that we will have multiple ATCBs and that we will have ATCBs that address both complete EHR technology and modular EHR technology.

Tomorrow is the day that we begin accepting applications. Hopefully we'll get the applications out tonight, so we have the applications ready before we're ready to accept. From conversations we believe that people, because these things have been published, they were published in the rules, this is not news; at least the first part of the application; to anybody.

Once the applications come in, once an application is complete with all of the parts we have 30 days to provide a decision on authorization. Each application will be reviewed by an internal review board for conformance to the standards and for competency to perform the testing and certification. After we authorize bodies we will post the names of those bodies and contact information on our Web site, the public Web site. Anybody can find it. By late summer we expect to have these ACTBs operational, no later than late summer. Vendors, developers, etc., anybody who wants to get their products or technology certified will work directly with the ATCBs. We expect by fall to have certified products in the market.

One of the things, another public service that we will have is what we're calling the CHPL; CHPL is the Certified Health IT Product List. It's where you go to find the source of truth. This will be a public service Web site where we have aggregated the list of all certified products, all certified technologies that are provided by the individual ATCB, so that a person who's interested either in purchasing or just finding out would be able to go to one place to find all of the information on the products, the information about the products, including what criteria they are certified to.

In addition, we will have a service later on, late fall/early 2011 that will provide a single number people can input if they have gone the modular route where they can input their modules and find out whether in the aggregate their modules satisfy the complete set of certification criterion, therefore, are eligible in terms of having certified EHR technology.

So that was the spin, the high level spin through both the rule making and the operational aspect.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's just ask if there are any quick, clarifying questions. Judy.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Just from a timing standpoint, for those folks who do want to qualify this year and start their qualification on the final regulations October 1st, which is the earliest a hospital could qualify, how is the timing going to work for that as related to the certified systems?

Carol Bean – ONC – Director, Certification Division
Well, I would say first that that is the beginning of the reporting period—

Judy Murphy – Aurora Healthcare – Vice President of Applications
Right. But if somebody wanted to start right away to get their money sooner rather than later—

Carol Bean – ONC – Director, Certification Division
I'm going to defer to—

Steve Posnack – ONC – Policy Analyst
I think that's a clarification that you'll get in the forthcoming rule making, so I would prefer not to comment on it.

Judy Murphy – Aurora Healthcare – Vice President of Applications
All right.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I would say that's a pregnant question in this community given the timeframe and the pressure; will certification during that reporting period or beyond be retrospectively applicable to the time that's been announced for the initiation. I know we're waiting with baited breath as well for response from the NPR and the other IFR.

Carol Bean – ONC – Director, Certification Division
And I assure you that we are all very sensitive to those timeframes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We know that. Okay. Other clarifying questions? If not, thank you very much for that. Very helpful. Very informative. Congratulations on getting the first response back. As I said, we look forward to the other two.

Carol Bean – ONC – Director, Certification Division
Sure.

Jonathan Perlin – Hospital Corporation of America – CMO & President
With that, let me turn it back to Judy Sparrow and so forth to get to public comments ... the opportunity.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. This is the public comment portion of the meeting. Tom, you're first in line.

Tom Leary – Healthcare Information and Management Systems Society
Hello, Tom Leary, Healthcare Information and Management Systems Society. On behalf of the board of directors and members of HIMS I'd like to submit a letter of support for the HIT Standards Committee Clinical Operations Vocabulary Taskforce's recommendations for a single, federal office, agency or entity to be responsible for ensuring the creation, maintenance, dissemination and accessibility of all controlled vocabularies and vocabulary value sets.

In addition, HIMS would like to emphasize that as you move forward on that activity to make sure that the excellent volunteer based work of the Health IT Standards Panel and the countless hours of volunteer hours, that that quality work gets pulled forward into the new activity. Thank you for an excellent discussion today. I've caught a few of you off-line on some of the other issues. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Tom. Dan.

Dan Rode – American Health Information Management Association
Thank you, Judy. Dan Rode. I'm with the American Health Information Management Association. Like Tom, I want to congratulate the sub-committee, the committee and the workgroup and the taskforce for the work that was done on the vocabulary recommendations. As you know, ourselves in AHIMA have been trying for about four years to get this subject recognized. It's so good that we finally are recognizing the needs for vocabularies, for terminologies, classifications and value sets.

With that said, I have to express that we cannot completely endorse your recommendation. We feel that it falls short on the basis of the fact that it only focuses on meaningful use and that the need for terminologies, classifications and the rest are much larger than that. The atmosphere and the environment that we're in requires that a governance of this type also include and look at some of the other things coming down the pike. Certainly, meaningful use is a priority and certainly it needs to be addressed, but we think to only set up an organization to address meaningful use falls short of the work that we've been trying to do and I think what you'll find is needed within the country.

With that said, also, we'd like to recommend that you consider and that the Office of the National Coordinator consider the National Library of Medicine as possibly the federal office that would oversee such a governance and that it have a FACA committee made up of data experts to work with it so that the decisions that have to be made between that group and between the Standards Committee can be done with a full exponent of information and experience.

I'll keep it at that because I forgot my glasses and I can't read anything else and you want to get out of here, but I will pass a copy of the letter and give an official copy to the chairman. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Thank you, Dan. We do have one commenter on the line.

Jane Brokel – NANDA-International – President Elect
I wish to thank the Clinical Operations Workgroup for the opportunity to provide feedback on the recommendations of the Vocabulary Taskforce. I am Jane Brokel, President Elect with NANDA-International. The remarks I present are approved by the international board of directors and represent the position of our global membership.

NANDA organizations began back in the late 1970s as the official professional organization in North America charged with the responsibilities for systematically developing, testing, coding and disseminating nursing diagnoses. Subsequently, the organization has become an international entity with members from more than 20 countries. The organization remains committed to the original charge and disseminates related research and knowledge through its quarterly publication, *The International Journal of Nursing Terminologies and Classifications*, the release of the printed and electronic versions of *The NANDA Nursing Diagnosis, Definitions and Classifications* and conferences that educate and share implementation outcomes.

With regards to the Taskforce recommendations, NANDA-I fully agrees and supports recommendations one and two. It also strongly recommends the inclusion of the following: The federal vocabulary entity should be meticulous in identifying, utilizing and building on the depth of this vocabulary knowledge, the next piece in the field. We believe it is in the best interest of the country for the new vocabulary entity to recognize and capitalize on knowledge in the field and to achieve the achievement of our vocabulary goal while minimizing the class.

NANDA-International is an excellent example of an organization that possesses an enormous depth of knowledge in the concept, development and maintenance of nursing vocabularies in the U.S. and globally. And NANDA-International is well positioned to see the life cycle management of nursing terminology value sets and code sets. We have 38 years of experience. Our concept development process is systematic and evidence based and adheres to accepted coding conventions. Our Diagnostic Development Committee meets regularly, has engaged thousands of nurses for all specialties throughout the world in development and expansion of taxonomy and includes concepts representative of the areas of nursing practice.

I will submit my comments to you and in conclusion, as a clear market leader in nursing diagnostic vocabulary, NANDA-International has developed linkages with other important nursing vocabularies, such as ... interventions and ... nursing data set. In conclusion, we strongly advocate the power of knowledge and expertise, such as available through NANDA-I to be utilized by the proposed federal vocabulary agency. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Ms. Brokel. I'll turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
The hour is late. I want to thank each of you, those folks on the line, for all of your input, a terrific and complex discussion today, an important discussion.

Obviously, all of us are waiting for the magic moment when the response to the publications in the Federal Register, both the ... and the IFR occurs. I mention this because that ... set of work and ... and Judy and David had some conversation off-line about the structure of our next meeting. Obviously ... imperative that we get together there may be some flexibility for a virtual meeting. If not, we'll query the group, but also respond, understanding that you all need lead time to make travel arrangements, etc.

John, do you have anything you'd like to add?

John Halamka – Harvard Medical School – Chief Information Officer
Again, I think it was a great discussion today. We raised all of the issues I wanted to raise about governance, about process, about making sure that there are clearly defined objectives and that there is policy developed in tandem with technology. We'll write about it on the blog tonight.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes. We have continuing conversation that will extend to our Clinical Operations Workgroup as a first order of business, as well, in our next meeting. With that, anything else from ... from anybody? Thank you all so much for your hard work and thank you, Judy and ONC staff, for all of your efforts. John.

John Halamka – Harvard Medical School – Chief Information Officer
Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We're adjourned.

Public Comment Received During the Meeting

1. On the CDA discussion, HITSP developed a modular approach using a "basis" of sections and entries, see C83 components

2. If we define policy as a plan of action adopted by an individual or social group. And we define technology as the tools that a society has developed in order to facilitate the solution of its practical problems. Policy and Technology are like brothers and sisters. They can have arguments and disagreements but they are genetically bound whether they like it or not. Policy and Technology share the same DNA whether we want to acknowledge that is a different story.

3. On behalf of NANDA-International, I wish to thank the —Clinical Operations Workgroup" for this opportunity to provide feedback on the Recommendations from the Vocabulary Task Force.

I am Jane Brokel the President-Elect for, NANDA-International. The remarks I present have been approved by the NANDA-International Board of Directors and represent the position of our global membership. The NANDA organization began in the late 1970s as the official professional organization in North America charged with the responsibilities for systematically developing, testing, coding, and disseminating nursing diagnoses. Subsequently the organization has become an international entity with members from more than 20 countries.

The organization remains committed to the original charge and disseminates related research and knowledge through:

1) Our quarterly publication – The International Journal of Nursing Terminologies and Classifications, and,
2) The release of print and electronic versions of NANDA-I Nursing Diagnoses: Definitions and Classifications every 2-3 years. The full taxonomy also includes defining characteristics related to patient assessments and the risk and related factors for each diagnostic concept – to inform the user during practice as clinical decision support interventions.
3) conferences to educate and share implementation outcomes

With regard to the task force recommendations:
For the 1.0: Life Cycle Management of Vocabularies, Value Sets and Code Sets.
2.0 Establishing an Authoritative Vocabulary Infrastructure
NANDA-I fully agrees and supports Recommendations 1 and 2 but also strongly recommends the inclusion of the following:
–The Federal Vocabulary entity should be meticulous in identifying, utilizing, and building on the depth of vocabulary knowledge and expertise in the field."

Our Rationale:
We believe it is in the best interest of the country for the new vocabulary entity to recognize and capitalize on knowledge in the field to speed the achievement of our vocabulary goal while minimizing the costs. The NANDA-International is an excellent example of an organization that possesses an enormous depth of knowledge in the concept development and maintenance of nursing vocabularies in the USA and globally. As such NANDA-International is well positioned to speed the Life Cycle Management of nursing vocabularies, value sets and code sets for nursing diagnostic concept development and refinement with the Authoritative Vocabulary Infrastructure. NANDA-International has more than 38 years of experience in systematic development, testing, and dissemination of a value set of concepts. Our concept development process is systematic and evidence based and adheres to accepted coding conventions. Our –Diagnostic Development Committee" meets regularly, has engaged thousands of nurses from all specialties throughout the world in the development and expansion of the taxonomy that includes concepts representative of all areas of nursing practice.

The NANDA-I concepts support nurses in a clinical reasoning process to evaluate the holistic needs of patients, families or communities, to make accurate decisions about care, and to document the health promotion requests, patient safety risks, and actual problems as "succinct" Diagnostic Concepts in the electronic health records and available for exchange between settings. The NANDA-I Concepts include culturally sensitive concepts and have been translated into (10) languages - Spanish, German, Japanese, Portuguese, French, and others including 3rd world countries.

NANDA-I continuously submits concept names for inclusion in the SNOMED-Clinical terms—many of which are the fully specified names and preferred names for nursing diagnoses.

As the clear market leader in the nursing "diagnostic" vocabulary, NANDA International has developed linkages with other important nursing vocabularies such as NOC patient desired outcomes, NIC interventions, and the Perioperative Nursing Data Set for surgery.

In conclusion, we strongly advocate that the power of knowledge and expertise such as that available through NANDA-I be utilized by the proposed federal vocabulary agency.

Thank you.

Jane M. Brokel, PhD, RN

President-Elect – NANDA International

1.0: Life Cycle Management of Vocabularies, Value Sets and Code Sets.
Recommendation 1.0: That a single federal office or agency should be responsible for ensuring the creation, maintenance, dissemination and accessibility of all controlled vocabularies, vocabulary value sets and subsets related to meaningful use.

2.0 Establishing an Authoritative Vocabulary Infrastructure
Recommendation 2.0: Establish an authoritative infrastructure for development, maintenance, and dissemination of standard value sets and subsets related to Meaningful Use